AUDIT STANDARDS COMPARISON TO THE INFANT FORMULA REGULATIONS

NOTE: This template does not include certain requirements that may be pertinent to determining compliance with 21 CFR Part 106 and 21 CFR Part 107 (including general requirements, definitions, and certain procedural requirements). "Shall" is used to state mandatory requirements. "Should" is used to state recommended or advisory procedures or to identify recommended equipment. In addition to meeting the applicable requirements of 21 CFR Parts 106 and 107, Infant Formula processors of foods intended for consumption in the U.S. are also required to comply with any other pertinent FDA regulatory requirements outside the elements included in the template (e.g., applicable requirements in 21 CFR part 117 related to current good manufacturing practices and preventive controls, 21 CFR Part 113, 114, and 108, as applicable).

PART 106 — INFANT FORMULA REQUIREMENTS PERTAINING TO CURRENT GOOD MANUFACTURING PRACTICE, QUALITY CONTROL PROCEDURES, QUALITY FACTORS, RECORDS AND REPORTS, AND NOTIFICATIONS	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
Subpart B—Current Good Manufacturing Practice				
§106.5 Current good manufacturing practice.				
(a) The regulations set forth in this subpart define the minimum current good manufacturing practices that are to be used in, and the facilities or controls that are to be used for, the manufacture, processing, packing, or holding of an infant formula. Compliance with these provisions is necessary to ensure that such infant formula provides the nutrients required under §107.100 of 21 CFR part 107 and is manufactured in a manner designed to prevent its adulteration. A liquid infant formula that is a thermally processed low-acid food packaged in a hermetically sealed container is also subject to the regulations in 21 CFR part 113, and an infant formula that is an acidified food, as defined in 21 CFR §114.3(b), is also subject to the regulations in 21 CFR part 114.				**Infant Formula processors are subject to the requirements of 21 CFR 117 subparts A, B, C, D, E, F, and G.**
(b) The failure to comply with any regulation in this subpart in the manufacture, processing, packing, or holding of an infant formula shall render such infant formula adulterated under section 412(a)(3) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 350a(a)(3)); the failure to comply with any regulation in 21 CFR part 113 in the manufacture, processing, packing, or holding of a liquid infant formula shall render such infant formula adulterated under section 412(a)(3) of the FD&C Act; and the failure to comply with any regulation in 21 CFR part 114 in the manufacture, processing, packing, or holding of an infant formula that is an acidified food shall render such infant formula adulterated under section 412(a)(3) of the FD&C Act.				
§106.6 Production and in-process control system.				

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PART 106 — INFANT FORMULA REQUIREMENTS PERTAINING TO CURRENT GOOD MANUFACTURING PRACTICE, QUALITY CONTROL PROCEDURES, QUALITY FACTORS, RECORDS AND REPORTS, AND NOTIFICATIONS	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
(a) A manufacturer shall conform to the requirements of this subpart by implementing a system of production and in-process controls. This production and in-process control system shall cover all stages of processing, from the receipt and acceptance of the raw materials, ingredients, and components through the storage and distribution of the finished product and shall be designed to ensure that all the requirements of this subpart are met.				
(b) The production and in-process control system shall be set out in a written plan or set of procedures that is designed to ensure that an infant formula is manufactured in a manner that will prevent adulteration of the infant formula.				
(c) At any point, step, or stage in the production process where control is necessary to prevent adulteration, a manufacturer shall:				
(1) Establish specifications to be met;				
(2) Monitor the production and in-process control point, step, or stage;				
(3) Establish a corrective action plan for use when a specification established in accordance with 21 CFR 106.6(c)(1) is not met;				
(4) Review the results of the monitoring required by 21 CFR 106.6(c)(2) of, and review and evaluate the public health significance of any deviation from specifications that have been established in accordance with 21 CFR 106.6(c)(1). For any specification established in accordance with 21 CFR 106.6(c)(1) that a manufacturer fails to meet, an individual qualified by education, training, or experience shall conduct a documented review and shall make a material disposition decision to reject the affected article, to reprocess or otherwise recondition the affected article, or to approve and release the article for use or distribution; and				

AUDIT STANDARDS COMPARISON TO THE INFANT FORMULA REGULATIONS

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PART 106 — INFANT FORMULA REQUIREMENTS PERTAINING TO CURRENT GOOD MANUFACTURING PRACTICE, QUALITY CONTROL PROCEDURES, QUALITY FACTORS, RECORDS AND REPORTS, AND NOTIFICATIONS	**Audit Standard Language**	**Analysis of Alignment of Audit Standard**	**Description of Gaps and Actions to Align**	**Additional Comments**
(5) Establish recordkeeping procedures, in accordance with 21 CFR §106.100(e)(3), that ensure that compliance with the requirements of 21 CFR 106.6 is documented.				
(d) Any article that fails to meet a specification established in accordance with 21 CFR 106.6(c)(1) shall be controlled under a quarantine system designed to prevent its use pending the completion of a documented review and material disposition decision.				
§106.10 Controls to prevent adulteration by workers.				
(a) A manufacturer shall employ sufficient personnel, qualified by education, training, or experience, to perform all operations, including all required recordkeeping, in the manufacture, processing, packing, and holding of each infant formula and to supervise such operations to ensure that the operations are correctly and fully performed.				
(b) Personnel working directly with infant formula, infant formula raw materials, infant formula packaging, or infant formula equipment or utensil contact surfaces shall practice good personal hygiene to protect the infant formula against contamination. Good personal hygiene includes:				
(1) Wearing clean outer garments and, as necessary, protective apparel such as head, face, hand, and arm coverings; and				
(2) Washing hands thoroughly in a hand washing facility with soap and running water at a suitable temperature before starting work, after each absence from the work station, and at any other time when the hands may become soiled or contaminated.				

AUDIT STANDARDS COMPARISON TO THE INFANT FORMULA REGULATIONS

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PART 106 — INFANT FORMULA REQUIREMENTS PERTAINING TO CURRENT GOOD MANUFACTURING PRACTICE, QUALITY CONTROL PROCEDURES, QUALITY FACTORS, RECORDS AND REPORTS, AND NOTIFICATIONS	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
(c) Any person who reports that he or she has, or appears by medical examination or supervisory observation to have, an illness, open lesion (including boils, sores, or infected wounds), or any other source of microbial contamination that creates a reasonable possibility that the safety of an infant formula may be adversely affected, shall be excluded from direct contact with ingredients, containers, closures, in-process materials, equipment, utensils, and infant formula product until the condition is corrected or determined by competent medical personnel not to jeopardize the safety of the infant formula.				
§106.20 Controls to prevent adulteration caused by facilities.				
(a) Buildings used in the manufacture, processing, packing, or holding of infant formula shall be maintained in a clean and sanitary condition and shall have space for the separation of incompatible operations, such as the handling of raw materials, the manufacture of the product, and packaging and labeling operations.				
(b) Separate areas or another system of separation, such as a computerized inventory control, a written card system, or an automated system of segregation, shall be used for holding raw materials, in-process materials, and final infant formula product at the following times:				
(1) Pending release for use in infant formula production or pending release of the final product;				
(2) After rejection for use in, or as, infant formula; and				
(3) After release for use in infant formula production or after release of the final product.				

AUDIT STANDARDS COMPARISON TO THE INFANT FORMULA REGULATIONS

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PART 106 — INFANT FORMULA REQUIREMENTS PERTAINING TO CURRENT GOOD MANUFACTURING PRACTICE, QUALITY CONTROL PROCEDURES, QUALITY FACTORS, RECORDS AND REPORTS, AND NOTIFICATIONS	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
(c) Lighting shall allow easy identification of raw materials, packaging, labeling, in-process materials, and finished products that have been released for use in infant formula production and shall permit the easy reading of instruments and controls necessary in processing, packaging, and laboratory analysis. Any lighting fixtures directly over or adjacent to exposed raw materials, in-process materials, or bulk (unpackaged) finished product shall be protected to prevent glass from contaminating the product in the event of breakage.				
(d) A manufacturer shall provide adequate ventilation or control equipment to minimize odors and vapors (including steam and noxious fumes) in areas where they may contaminate the infant formula; and shall minimize the potential for contamination of raw materials, in-process materials, final product infant formula, packing materials, and infant formula-contact surfaces, through the use of appropriate measures, which may include the use of air filtration.				
(e) All rodenticides, insecticides, fungicides, fumigating agents, and cleaning and sanitizing agents shall be stored and used in a manner that protects against contamination of infant formula.				
(f) Potable water used in the manufacture of infant formula shall meet the standards prescribed in the Environmental Protection Agency's (EPA's) Primary Drinking Water regulations in 40 CFR part 141, except that the water used in infant formula manufacturing shall not be fluoridated or shall be defluoridated to a level as low as possible prior to use.				
(1) The water shall be supplied under continuous positive pressure in a plumbing system that is free of defects that could contaminate an infant formula.				

AUDIT STANDARDS COMPARISON TO THE INFANT FORMULA REGULATIONS

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PART 106 — INFANT FORMULA REQUIREMENTS PERTAINING TO CURRENT GOOD MANUFACTURING PRACTICE, QUALITY CONTROL PROCEDURES, QUALITY FACTORS, RECORDS AND REPORTS, AND NOTIFICATIONS	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
(2) A manufacturer shall test representative samples of the potable water drawn at a point in the system at which the water is in the same condition that it will be when it is used in infant formula manufacturing.				
(3) A manufacturer shall conduct the tests required by 21 CFR 106.20(f)(2) with sufficient frequency to ensure that the water meets the EPA's Primary Drinking Water Regulations but shall not conduct these tests less frequently than annually for chemical contaminants, every 4 years for radiological contaminants, and weekly for bacteriological contaminants.				
(4) A manufacturer shall make and retain records, in accordance with §106.100(f)(1), of the frequency and results of testing of the water used in the production of infant formula.				
(g) There shall be no backflow from, or cross-connection between, piping systems that discharge waste water or sewage and piping systems that carry water for infant formula manufacturing.				
(h) Only culinary steam shall be used at all direct infant formula product contact points. Culinary steam shall be in compliance with the 3-A Sanitary Standards, No. 60903, which is incorporated by reference at 21 CFR §106.160. Boiler water additives in the steam shall be used in accordance with 21 CFR §173.310.				

AUDIT STANDARDS COMPARISON TO THE INFANT FORMULA REGULATIONS

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PART 106 — INFANT FORMULA REQUIREMENTS PERTAINING TO CURRENT GOOD MANUFACTURING PRACTICE, QUALITY CONTROL PROCEDURES, QUALITY FACTORS, RECORDS AND REPORTS, AND NOTIFICATIONS	**Audit Standard Language**	**Analysis of Alignment of Audit Standard**	**Description of Gaps and Actions to Align**	**Additional Comments**
(i) Each infant formula manufacturing site shall provide its employees with readily accessible toilet facilities and hand washing facilities that include hot and cold water, soap or detergent, single-service towels or air dryers in toilet facilities. These facilities shall be maintained in good repair and in a sanitary condition at all times. These facilities shall provide for proper disposal of the sewage. Doors to the toilet facility shall not open into areas where infant formula, ingredients, containers, or closures are processed, handled, or stored, except where alternate means have been taken to protect against contamination.				
§106.30 Controls to prevent adulteration caused by equipment or utensils.				
(a) A manufacturer shall ensure that equipment and utensils used in the manufacture, processing, packing, or holding of an infant formula are of appropriate design and are installed to facilitate their intended function and their cleaning and maintenance.				

AUDIT STANDARDS COMPARISON TO THE INFANT FORMULA REGULATIONS

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PART 106 — INFANT FORMULA REQUIREMENTS PERTAINING TO CURRENT GOOD MANUFACTURING PRACTICE, QUALITY CONTROL PROCEDURES, QUALITY FACTORS, RECORDS AND REPORTS, AND NOTIFICATIONS	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
(b) A manufacturer shall ensure that equipment and utensils used in the manufacture, processing, packing, or holding of an infant formula are constructed so that surfaces that contact ingredients, in-process materials, or infant formula are made of nontoxic materials and are not reactive or absorptive. A manufacturer shall ensure that such equipment and utensils are designed to be easily cleanable and to withstand the environment of their intended use and that all surfaces that contact ingredients, in-process materials, or infant formula are cleaned and sanitized, as necessary, and are maintained to protect infant formula from being contaminated by any source. All sanitizing agents used on such equipment and utensils that are regulated as pesticide chemicals under 21 U.S.C. 346a(a) shall comply with the Environmental Protection Agency's regulations established under such section, and all other such sanitizers shall comply with all applicable Food and Drug Administration laws and regulations.				
(c) A manufacturer shall ensure that any substance, such as a lubricant or a coolant, that is required for operation of infant formula manufacturing equipment and which would render the infant formula adulterated if such substance were to come in contact with the formula, does not come in contact with formula ingredients, containers, closures, in-process materials, or with infant formula product during the manufacture of an infant formula.				

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PART 106 — INFANT FORMULA REQUIREMENTS PERTAINING TO CURRENT GOOD MANUFACTURING PRACTICE, QUALITY CONTROL PROCEDURES, QUALITY FACTORS, RECORDS AND REPORTS, AND NOTIFICATIONS	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
(d) A manufacturer shall ensure that each instrument used for measuring, regulating, or controlling mixing time and speed, temperature, pressure, moisture, water activity, or other parameter at any point, step, or stage where control is necessary to prevent adulteration of an infant formula during processing is accurate, easily read, properly maintained, and present in sufficient number for its intended use.				
(1) The instruments and controls shall be calibrated against a known reference standard at the time of or before first use and thereafter at routine intervals, as specified in writing by the manufacturer of the instrument or control, or as otherwise deemed necessary to ensure the accuracy of the instrument or control. The known reference standard shall be certified for accuracy at the intervals specified in writing by the manufacturer of the instrument or control, or at routine intervals otherwise deemed necessary to ensure the accuracy of the instrument or control. A manufacturer shall make and retain records of the calibration activities in accordance with §106.100(f)(2).				
(2) Instruments and controls that cannot be adjusted to agree with the reference standard shall be repaired or replaced.				
(3) If calibration of an instrument shows a failure to meet a specification for a point where control is deemed necessary to prevent adulteration of infant formula product, a written evaluation of all affected product, and of any actions that need to be taken with respect to that product, shall be made, in accordance with §106.100(f)(2).				
(e) The following provisions apply to thermal processing and cold storage of infant formulas:				

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(1) Equipment and procedures for thermal processing of infant formula packaged in hermetically sealed containers shall conform to the requirements in 21 CFR parts 108 and 113.				
(2)(i) Except as provided in 21 CFR 106.30(e)(2)(ii), a manufacturer shall maintain all areas of cold storage at a temperature of 40 °F (4.4 °C) or below.				
(ii) A manufacturer may maintain a cold storage area for an in-process infant formula or for a final infant formula at a temperature not to exceed 45 °F (7.2 °C) for a defined period of time provided that the manufacturer has scientific data and other information to demonstrate that the time and temperature conditions of such storage are sufficient to ensure that there is no significant growth of microorganisms of public health significance during the period of storage of the in-process or final infant formula product.				
(3)(i) Cold storage compartments and thermal processing equipment shall be equipped with easily readable, accurate temperature-indicating devices.				
(ii) A manufacturer shall ensure that the temperature of each cold storage compartment is maintained by:				
(A) Monitoring the temperature of the cold storage compartment on a temperature-indicating device and recording this temperature in a record with such frequency as is necessary to ensure that temperature control is maintained;				
(B) Equipping the cold storage compartment with one or more temperature-recording devices that will reflect, on a continuing basis, the true temperature, within the compartment;				

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(C) Equipping the cold storage compartment with a high temperature alarm that has been validated to function properly and recording the temperature in a record with such frequency as is necessary to ensure that temperature control is maintained; or				
(D) Equipping the cold storage compartment with a maximum-indicating thermometer that has been validated to function properly and recording this temperature in a record with such frequency as is necessary to ensure that temperature control is maintained.				
(iii) A manufacturer shall, in accordance with §106.100(f)(3), make and retain records of the temperatures recorded in compliance with §106.30(e)(3)(ii).				
(4) When a manufacturer uses a temperature-recording device for a cold storage compartment, such device shall not read lower than the reference temperature-indicating device.				
(5) A manufacturer shall monitor the temperature in thermal processing equipment at points where temperature control is necessary to prevent adulteration. Such monitoring shall be at such frequency as is required by regulation or is necessary to ensure that temperature control is maintained.				
(f) A manufacturer shall ensure that equipment and utensils used in the manufacture of infant formula are cleaned, sanitized, and maintained at regular intervals to prevent adulteration of the infant formula.				
(1) An individual qualified by education, training, or experience to conduct such a review shall review all cleaning, sanitizing, and maintenance to ensure that it has been satisfactorily completed.				

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PART 106 — INFANT FORMULA REQUIREMENTS PERTAINING TO CURRENT GOOD MANUFACTURING PRACTICE, QUALITY CONTROL PROCEDURES, QUALITY FACTORS, RECORDS AND REPORTS, AND NOTIFICATIONS	**Audit Standard Language**	**Analysis of Alignment of Audit Standard**	**Description of Gaps and Actions to Align**	**Additional Comments**
(2) A manufacturer shall make and retain records on equipment cleaning, sanitizing, and maintenance, in accordance with §106.100(f)(4).				
(g) A manufacturer shall ensure that compressed air or other gases that are mechanically introduced into infant formula, that are used to clean any equipment, or that come into contact with any other surface that contacts ingredients, in-process materials, or infant formula product are treated in such a way that their use will not contaminate the infant formula with unlawful or other chemical, physical, or microbiological contaminants. When compressed gases are used at product filling machines to replace air removed from the headspace of containers, a manufacturer shall install, as close as practical to the end of the gas line that feeds gas into the space, a filter capable of retaining particles 0.5 micrometer or smaller.				
§106.35 Controls to prevent adulteration due to automatic (mechanical or electronic) equipment.				
(b) All systems shall be designed, installed, tested, and maintained in a manner that will ensure that they are capable of performing their intended function and of producing or analyzing infant formula in accordance with this subpart and subpart C of 21 CFR part 106.				
(1) A manufacturer shall ensure, at any point, step, or stage where control is necessary to prevent adulteration of the infant formula, that all hardware is routinely inspected and checked according to written procedures and that hardware that is capable of being calibrated is routinely calibrated according to written procedures.				

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(2) A manufacturer shall check and document the accuracy of input into, and output generated by, any system used in the production or quality control of an infant formula to ensure that the infant formula is not adulterated. The degree and frequency of input/output verification shall be based on the complexity and reliability of the system and the level of risk associated with the safe operation of the system.				
(3) A manufacturer shall ensure that each system is validated prior to the release for distribution of any infant formula manufactured using the system.				
(4) A manufacturer shall ensure that any system that is modified is revalidated following the modification and prior to the release for distribution of any infant formula manufactured using the modified system. All modifications to software shall be made by a designated individual and shall be checked by the infant formula manufacturer to ensure that infant formula that is produced or analyzed using the modified software complies with this subpart and with subpart C of 21 CFR Part 106.				
(c) A manufacturer shall make and retain records, in accordance with §106.100(f)(5), concerning mechanical or electronic equipment.				
§106.40 Controls to prevent adulteration caused by ingredients, containers, and closures.				

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(a) The only substances that may be used in an infant formula are substances that are safe and suitable for use in infant formula under the applicable food safety provisions of the Federal Food, Drug, and Cosmetic Act; that is, a substance is used in accordance with the Agency's food additive regulations, is generally recognized as safe (GRAS) for such use, or is authorized by a prior sanction.				
(b) Infant formula containers and closures shall not be reactive or absorptive so as to affect the safety of the infant formula. The following substances may be used as packaging material that comes in contact with an infant formula:				
(1) A food additive that is the subject of a regulation issued under section 409(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 348(c)) and is used consistent with the conditions of use of that regulation;				
(2) A food contact substance that is the subject of an effective notification under section 409(h) of the Federal Food, Drug, and Cosmetic Act and is used consistent with the conditions of use in that notification;				
(3) A substance that is exempt from regulation as a food additive under 21 CFR §170.39 and its use conforms to the use identified in the exemption letter;				
(4) A substance that is generally recognized as safe for use in or on infant formula or for use in infant formula packaging;				
(5) A substance the use of which is authorized by a prior sanction from the Food and Drug Administration or from the U.S. Department of Agriculture; and				

AUDIT STANDARDS COMPARISON TO THE INFANT FORMULA REGULATIONS

NOTE: This template does not include certain requirements that may be pertinent to determining compliance with 21 CFR Part 106 and 21 CFR Part 107 (including general requirements, definitions, and certain procedural requirements). "Shall" is used to state mandatory requirements. "Should" is used to state recommended or advisory procedures or to identify recommended equipment. In addition to meeting the applicable requirements of 21 CFR Parts 106 and 107, Infant Formula processors of foods intended for consumption in the U.S. are also required to comply with any other pertinent FDA regulatory requirements outside the elements included in the template (e.g., applicable requirements in 21 CFR part 117 related to current good manufacturing practices and preventive controls, 21 CFR Part 113, 114, and 108, as applicable).

PART 106 — INFANT FORMULA REQUIREMENTS PERTAINING TO CURRENT GOOD MANUFACTURING PRACTICE, QUALITY CONTROL PROCEDURES, QUALITY FACTORS, RECORDS AND REPORTS, AND NOTIFICATIONS	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
(6) A substance that is not a food additive within the meaning of section 201(s) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(s)) because the substance is not reasonably expected to become a component of food or otherwise affect the characteristics of food.				
(c) Ingredients, containers, and closures used in the manufacture of infant formula shall be identified with a lot number to be used in recording their disposition.				
(d) A manufacturer shall develop written specifications for ingredients, containers, and closures used in manufacturing infant formula and shall develop and follow written procedures to determine whether all ingredients, containers, and closures meet these specifications. When any specification is not met, an individual qualified by education, training, or experience shall conduct a documented review, shall determine whether a failure to meet such a specification could result in an adulterated infant formula, and shall make and document a material disposition decision to reject the ingredient, container, or closure or the affected infant formula; to reprocess or otherwise recondition the ingredient, container, or closure or the affected infant formula; or to approve and release the ingredient, container, or closure or the affected infant formula for use.				
(e) Ingredients, containers, and closures shall be stored in separate areas or separated by a system of segregation, such as a computerized inventory control, a written card system, or an automated system of segregation, clearly designated for materials pending release for use; materials released for use; or materials rejected for use in infant formula production.				

AUDIT STANDARDS COMPARISON TO THE INFANT FORMULA REGULATIONS

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PART 106 — INFANT FORMULA REQUIREMENTS PERTAINING TO CURRENT GOOD MANUFACTURING PRACTICE, QUALITY CONTROL PROCEDURES, QUALITY FACTORS, RECORDS AND REPORTS, AND NOTIFICATIONS	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
(1) Any lot of an ingredient, a container, or a closure that does not meet the manufacturer's specifications shall be quarantined under a system designed to prevent its use in the manufacture of infant formula until an individual qualified by education, training, or experience has conducted a documented review, has determined whether such failure could result in an adulterated infant formula, and has made and documented a material disposition decision to reject the ingredient, container, closure, or the affected infant formula; to reprocess or otherwise recondition the ingredient, container, closure, or the affected infant formula; or to approve and release the ingredient, container, closure, or the affected infant formula for use.				
(2) Any ingredient, container, or closure that has been reprocessed or otherwise reconditioned shall be the subject of a documented review and material disposition decision by an individual qualified by education, training, or experience to determine whether it may be released for use.				
(3) A manufacturer shall not reprocess or otherwise recondition an ingredient, container, or closure rejected because it is contaminated with microorganisms of public health significance or other contaminants, such as heavy metals.				

AUDIT STANDARDS COMPARISON TO THE INFANT FORMULA REGULATIONS

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PART 106 — INFANT FORMULA REQUIREMENTS PERTAINING TO CURRENT GOOD MANUFACTURING PRACTICE, QUALITY CONTROL PROCEDURES, QUALITY FACTORS, RECORDS AND REPORTS, AND NOTIFICATIONS	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
(f) If an ingredient, container, or closure that complies with a manufacturer's specifications, or that has been released for use following a material review and disposition decision, is subsequently exposed to air, heat, or other conditions that may adversely affect it, or if a manufacturer reasonably believes that an ingredient, container, or closure that complies with a manufacturer's specifications, or that has been released for use following a material review and disposition decision, has been exposed to air, heat, or other conditions that may adversely affect it, the ingredient, container, or closure shall be quarantined under a system designed to prevent its use in the manufacture of infant formula until an individual qualified by education, training, or experience has conducted a documented review and has made and documented a material disposition decision to reject the ingredient, container, or closure; to reprocess or otherwise recondition the ingredient, container, or closure; or to approve and release the ingredient, container, or closure for use.				
(1) Any ingredient, container, or closure that is reprocessed or otherwise reconditioned shall be retested or reexamined and be the subject of a documented review and material disposition decision by an individual qualified by education, training, or experience to determine whether the ingredient, container, or closure should be rejected, further reprocessed or otherwise further reconditioned, or approved and released for use.				
(2) Any rejected ingredient, container, or closure shall be clearly identified as having been rejected for use in infant formula manufacturing or processing operations and shall be controlled under a quarantine system designed to prevent its use in infant formula manufacturing or processing operations.				

AUDIT STANDARDS COMPARISON TO THE INFANT FORMULA REGULATIONS

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PART 106 — INFANT FORMULA REQUIREMENTS PERTAINING TO CURRENT GOOD MANUFACTURING PRACTICE, QUALITY CONTROL PROCEDURES, QUALITY FACTORS, RECORDS AND REPORTS, AND NOTIFICATIONS	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
(3) Any ingredient, container, or closure that has not been manufactured, packaged, labeled, or held under conditions to prevent adulteration under section 402(a)(1) through (a)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342(a)(1) through (a)(4)) shall not be approved and released for use.				
(g) A manufacturer shall make and retain records, in accordance with §106.100(f)(6), on the ingredients, containers, and closures used in the manufacture of infant formula.				
§106.50 Controls to prevent adulteration during manufacturing.				
(a) A manufacturer shall prepare and follow a written master manufacturing order that establishes controls and procedures for the production of an infant formula.				
(1) The manufacturer shall make and retain records, in accordance with §106.100(e), that include complete information relating to the production and control of the production aggregate. An individual qualified by education, training, or experience shall conduct an investigation of any deviations from the master manufacturing order and document any corrective action taken.				
(2) Changes made to the master manufacturing order shall be reviewed and approved by a responsible official and include an evaluation of the effect of the change on the nutrient content and the suitability of the formula for infants.				

AUDIT STANDARDS COMPARISON TO THE INFANT FORMULA REGULATIONS

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PART 106 — INFANT FORMULA REQUIREMENTS PERTAINING TO CURRENT GOOD MANUFACTURING PRACTICE, QUALITY CONTROL PROCEDURES, QUALITY FACTORS, RECORDS AND REPORTS, AND NOTIFICATIONS	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
(b) A manufacturer shall establish controls to ensure that each raw or in-process ingredient required by the master manufacturing order is examined by one person and checked by a second person or system. This checking shall ensure that the correct ingredient is added during the manufacturing process, that the ingredient has been released for use in infant formula, and that the correct weight or measure of the ingredient is added to the production unit.				
(c) A manufacturer shall establish a system of identification for the contents of all compounding and storage containers, processing lines, and major equipment used during the manufacture of a production aggregate of an infant formula. The system shall permit the identification of the processing stage and the unique identification number for the particular production unit or production aggregate of infant formula.				
(d) A manufacturer shall establish controls to ensure that the nutrient levels required by 21 CFR §107.100 are maintained in the formula, and that the formula is not contaminated with microorganisms or other contaminants. Such controls shall include:				
(1) The mixing time; the speed, temperature, and flow rate of product; and other critical parameters necessary to ensure the addition of required ingredients to, and the homogeneity of, the formula;				
(2) The spray-drying process for powdered infant formula, including the filtering of the intake air before heating, to prevent microbial and other contamination;				
(3) The removal of air from the finished product to ensure that nutrient deterioration does not occur;				

AUDIT STANDARDS COMPARISON TO THE INFANT FORMULA REGULATIONS

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PART 106 — INFANT FORMULA REQUIREMENTS PERTAINING TO CURRENT GOOD MANUFACTURING PRACTICE, QUALITY CONTROL PROCEDURES, QUALITY FACTORS, RECORDS AND REPORTS, AND NOTIFICATIONS	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
(4) Ensuring that each container of finished product is properly sealed. Such controls shall involve use of established procedures, specifications, and intervals of examination that are designed by qualified individuals and are sufficient to:				
(i) Detect visible closure or seal defects, and				
(ii) Determine closure strength through destructive testing. A manufacturer of a liquid infant formula that is a thermally processed low-acid food packaged in a hermetically sealed container shall perform such closure integrity testing in accordance with 21 CFR §113.60(a).				
(e) A manufacturer shall establish controls that ensure that the equipment used at points where control is deemed necessary to prevent adulteration is monitored, so that personnel will be alerted to malfunctions.				
(f) A manufacturer shall establish controls for in-process material as follows:				
(1) For any specification established in accordance with §106.6(c)(1) that a manufacturer fails to meet for in-process material, an individual qualified by education, training, or experience shall conduct a documented review and shall make a material disposition decision to reject the affected in-process material, to reprocess or otherwise recondition the affected in-process material, or to approve and release the affected in-process material for use or distribution;				

AUDIT STANDARDS COMPARISON TO THE INFANT FORMULA REGULATIONS

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PART 106 — INFANT FORMULA REQUIREMENTS PERTAINING TO CURRENT GOOD MANUFACTURING PRACTICE, QUALITY CONTROL PROCEDURES, QUALITY FACTORS, RECORDS AND REPORTS, AND NOTIFICATIONS	**Audit Standard Language**	**Analysis of Alignment of Audit Standard**	**Description of Gaps and Actions to Align**	**Additional Comments**
(2) Pending a documented review and material disposition decision, any in-process material that fails to meet any specification established in accordance with §106.6(c)(1) shall be clearly identified as such and shall be controlled under a quarantine system designed to prevent its use in manufacturing or processing operations until completion of the documented review and material disposition decision;				
(3) Any in-process material that has been reprocessed or otherwise reconditioned shall be the subject of a documented review and material disposition decision by an individual qualified by education, training, or experience to determine whether it may be released for use; and				
(4) Any rejected in-process material shall be clearly identified as having been rejected for use in infant formula and shall be controlled under a quarantine system designed to prevent its use in infant formula manufacturing or processing operations.				
§106.55 Controls to prevent adulteration from microorganisms.				
(a) A manufacturer of infant formula shall establish a system of process controls covering all stages of processing that is designed to ensure that infant formula does not become adulterated due to the presence of microorganisms in the formula or in the processing environment.				
(b) A manufacturer of liquid infant formula shall comply, as appropriate, with the procedures specified in 21 CFR part 113 for thermally processed low-acid foods packaged in hermetically sealed containers and 21 CFR part 114 for acidified foods.				

AUDIT STANDARDS COMPARISON TO THE INFANT FORMULA REGULATIONS

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<table>
<tr><th>PART 106 — INFANT FORMULA REQUIREMENTS PERTAINING TO CURRENT GOOD MANUFACTURING PRACTICE, QUALITY CONTROL PROCEDURES, QUALITY FACTORS, RECORDS AND REPORTS, AND NOTIFICATIONS</th><th>Audit Standard Language</th><th>Analysis of Alignment of Audit Standard</th><th>Description of Gaps and Actions to Align</th><th>Additional Comments</th></tr>
<tr><td>(c) A manufacturer of powdered infant formula shall test representative samples of each production aggregate of powdered infant formula at the final product stage, before distribution, to ensure that each production aggregate meets the microbiological quality standards in the table in 21 CFR 106.55(e).</td><td></td><td></td><td></td><td></td></tr>
<tr><td>(d) A manufacturer shall make and retain records, in accordance with §106.100(e)(5)(ii) and (f)(7), on the testing of infant formulas for microorganisms.</td><td></td><td></td><td></td><td></td></tr>
<tr><td>(e) A powdered infant formula that contains any microorganism that exceeds the M value listed for that microorganism in the table in 21 CFR 106.55(e) shall be deemed adulterated under sections 402(a)(1), 402(a)(4), and 412(a)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350a(a)(3)). The Food and Drug Administration will determine compliance with the M values listed below using the latest edition of the Bacteriological Analytical Manual (BAM) (http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/BacteriologicalAnalyticalManualBAM/default.htm)
<table>
<tr><th>Microorganism</th><th>n[1]</th><th>Sample size</th><th>M value</th></tr>
<tr><td>Cronobacter spp.</td><td>30</td><td>10 g (grams)</td><td>[2]0.</td></tr>
<tr><td>Salmonella spp.</td><td>60</td><td>25 g</td><td>[2]0.</td></tr>
</table>
[1] Number of samples

[2] None detected</td><td></td><td></td><td></td><td></td></tr>
</table>

AUDIT STANDARDS COMPARISON TO THE INFANT FORMULA REGULATIONS

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PART 106 — INFANT FORMULA REQUIREMENTS PERTAINING TO CURRENT GOOD MANUFACTURING PRACTICE, QUALITY CONTROL PROCEDURES, QUALITY FACTORS, RECORDS AND REPORTS, AND NOTIFICATIONS	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
§106.60 Controls to prevent adulteration during packaging and labeling of infant formula.				
(a) A manufacturer shall examine packaged and labeled infant formula during finishing operations to ensure that all containers and packages in the production aggregate have the correct label, the correct use-by date, and the correct code established under §106.80.				
(b) Labels shall be designed, printed, and applied so that the labels remain legible and attached during the conditions of processing, storage, handling, distribution, and use.				
(c) Packaging used to hold multiple containers of an infant formula product shall be labeled as follows:				
(1) Where all containers are the same infant formula product and all bear the same code established under §106.80, the packaging label shall include the product name, the name of the manufacturer, distributor, or shipper, and the code established under §106.80.				
(2) Where the containers are not the same infant formula product or do not all bear the same code established under §106.80, the packaging label shall:				
(i) Include the product name of each product, the name of the manufacturer, distributor, or shipper of each product, the code established under 21 CFR §106.80 for each product, and a "use by" date that is no later than the "use by" date of the container exhibiting the closest "use by" date applied to satisfy the requirement of 21 CFR §107.20(c); or				

AUDIT STANDARDS COMPARISON TO THE INFANT FORMULA REGULATIONS

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PART 106 — INFANT FORMULA REQUIREMENTS PERTAINING TO CURRENT GOOD MANUFACTURING PRACTICE, QUALITY CONTROL PROCEDURES, QUALITY FACTORS, RECORDS AND REPORTS, AND NOTIFICATIONS	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
(ii) Include a unique identification number assigned by the packager, provided that the distributor of the package maintains a record linked to such unique number that identifies the product name of each product, the name of the manufacturer, distributor, or shipper of each product, the code established under 21 CFR §106.80 for each product, and the "use by" date for each product applied to satisfy the requirement of 21 CFR §107.20(c).				
§106.70 Controls on the release of finished infant formula.				
(a) A manufacturer shall control under a quarantine system designed to prevent use or distribution of each production aggregate of infant formula until it determines that the production aggregate meets all of the manufacturer's specifications, including those adopted to meet the standards of §106.55 on microbiological contamination and of §106.91(a) on quality control procedures, or until the documented review of the failure to meet any of the manufacturer's specifications finds that the failure does not result in, or could not lead to, adulteration of the product.				

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PART 106 — INFANT FORMULA REQUIREMENTS PERTAINING TO CURRENT GOOD MANUFACTURING PRACTICE, QUALITY CONTROL PROCEDURES, QUALITY FACTORS, RECORDS AND REPORTS, AND NOTIFICATIONS	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
(b) Any production aggregate of infant formula that fails to meet any of the manufacturer's specifications shall be quarantined under a system designed to prevent its use in the manufacture of infant formula or its distribution until an individual qualified by education, training, or experience has conducted a documented review and has made and documented a material disposition decision to reject the infant formula; to reprocess or otherwise recondition the infant formula; or to approve and release the infant formula. Any production aggregate of infant formula that is reprocessed or otherwise reconditioned shall be the subject of a documented review and material disposition decision by an individual qualified by education, training, or experience to determine whether it may be released for use or distribution.				
(c) Any rejected infant formula shall be clearly identified as having been rejected for use and shall be controlled under a quarantine system designed to prevent its release or distribution.				
(d) A production aggregate of infant formula, including a reprocessed or reconditioned production aggregate, that does not meet the nutrient requirements of section 412(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350a(i)) or that has not been manufactured, packaged, labeled, and held under conditions to prevent adulteration under sections 402(a)(1) through (a)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342(a)(1) through (a)(4)) shall not be approved and released for distribution.				
§106.80 Traceability.				

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PART 106 — INFANT FORMULA REQUIREMENTS PERTAINING TO CURRENT GOOD MANUFACTURING PRACTICE, QUALITY CONTROL PROCEDURES, QUALITY FACTORS, RECORDS AND REPORTS, AND NOTIFICATIONS	**Audit Standard Language**	**Analysis of Alignment of Audit Standard**	**Description of Gaps and Actions to Align**	**Additional Comments**
Each production aggregate of infant formula shall be coded with a sequential number that identifies the product and the establishment where the product was packed and that permits tracing of all stages of manufacture of that production aggregate, including the year, the days of the year, and the period during those days that the product was packed, and the receipt and handling of raw materials used.				
§106.90 Audits of current good manufacturing practice.				
(a) A manufacturer of an infant formula, or an agent of such manufacturer, shall conduct regularly scheduled audits to determine whether the manufacturer has complied with the current good manufacturing practice regulations in this subpart. Such audits shall be conducted at a frequency that is required to ensure compliance with such regulations.				
(b) The audits required by 21 CFR 106.90(a) shall be performed by an individual or a team of individuals who, as a result of education, training, or experience, is knowledgeable in all aspects of infant formula production and of the Agency's regulations concerning current good manufacturing practice that such individual or team is responsible for auditing. This individual or team of individuals shall have no direct responsibility for the matters that such individual or team is auditing and shall have no direct interest in the outcome of the audit.				
Subpart C—Quality Control Procedures				
§106.91 General quality control.				
(a) During manufacture, a manufacturer shall test each production aggregate for nutrients as follows:				

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(1) Each nutrient premix used in the manufacture of an infant formula shall be tested for each nutrient (required under 21 CFR §107.100 or otherwise added by the manufacturer) that the manufacturer is relying on the premix to provide, to ensure that the premix is in compliance with the manufacturer's specifications;				
(2) During the manufacturing process, after the addition of the premix, or at the final product stage but before distribution, each production aggregate of infant formula shall be tested for at least one indicator nutrient for each of the nutrient premixes used in the infant formula to confirm that the nutrients supplied by each of the premixes are present, in the proper concentration, in the production aggregate of infant formula.				
(3) At the final product stage, before distribution of an infant formula, each production aggregate shall be tested for vitamins A, C, E, and thiamin.				
(4) During the manufacturing process or at the final product stage, before distribution, each production aggregate shall be tested for all nutrients required to be included in such formula under 21 CFR §107.100 for which testing is not conducted for compliance with 21 CFR 106.91(a)(1) or (a)(3) and for any nutrient added by the manufacturer for which testing is not conducted for compliance with 21 CFR 106.91(a)(1).				
(b) A manufacturer shall test each production aggregate of finished product for nutrients as follows:				

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PART 106 — INFANT FORMULA REQUIREMENTS PERTAINING TO CURRENT GOOD MANUFACTURING PRACTICE, QUALITY CONTROL PROCEDURES, QUALITY FACTORS, RECORDS AND REPORTS, AND NOTIFICATIONS	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
(1)(i) For an infant formula that is a new infant formula the manufacturer shall collect, from each manufacturing site and at the final product stage, a representative sample of the first production aggregate of packaged, finished formula in each physical form (powder, ready-to-feed, or concentrate) and evaluate the levels of all nutrients required under21 CFR §107.100 and all other nutrients added by the manufacturer. The manufacturer shall repeat such testing every 4 months thereafter throughout the shelf life of the product.				
(ii) The Food and Drug Administration will exempt the manufacturer from the requirements of paragraph (b)(1)(i) of 21 CFR §106.91 if the manufacturer of a new infant formula requests an exemption and provides analytical data, as required under 21 CFR §106.120(b)(7), that demonstrates 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. A manufacturer exempt from the requirements of 21 CFR §106.91(b)(1)(i) would be required to test the first production aggregate according to the requirements of 21 CFR §106.91(b)(2).				
(2) The manufacturer shall collect, from each manufacturing site and at the final product stage, a representative sample of each subsequent production aggregate of packaged, finished formula in each physical form (powder, ready-to-feed, or concentrate) and evaluate the levels of all nutrients required under 21 CFR §107.100 and all other nutrients added by the manufacturer. The manufacturer shall repeat such testing at the end of the shelf life of the product.				

AUDIT STANDARDS COMPARISON TO THE INFANT FORMULA REGULATIONS

NOTE: This template does not include certain requirements that may be pertinent to determining compliance with 21 CFR Part 106 and 21 CFR Part 107 (including general requirements, definitions, and certain procedural requirements). "Shall" is used to state mandatory requirements. "Should" is used to state recommended or advisory procedures or to identify recommended equipment. In addition to meeting the applicable requirements of 21 CFR Parts 106 and 107, Infant Formula processors of foods intended for consumption in the U.S. are also required to comply with any other pertinent FDA regulatory requirements outside the elements included in the template (e.g., applicable requirements in 21 CFR part 117 related to current good manufacturing practices and preventive controls, 21 CFR Part 113, 114, and 108, as applicable).

PART 106 — INFANT FORMULA REQUIREMENTS PERTAINING TO CURRENT GOOD MANUFACTURING PRACTICE, QUALITY CONTROL PROCEDURES, QUALITY FACTORS, RECORDS AND REPORTS, AND NOTIFICATIONS	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
(3) If the results of the testing required by 21 CFR §106.91(b)(1) do not substantiate the shelf life of the infant formula, the manufacturer shall address, as appropriate, all production aggregates of formula released and pending release for distribution that are implicated by the testing results, such as by conducting the testing required by 21 CFR §106.91(b)(1) on a subsequently produced production aggregate to substantiate the shelf life of the infant formula or revising the use by date for such product so that such date is substantiated by the stability testing results.				
(4) If results of the testing required by 21 CFR §106.91(b)(2) show that any required nutrient is not present in the production aggregate of infant formula at the level required by 21 CFR §107.100 or that any nutrient added by the manufacturer is not present at the level declared on the label of the production aggregate of infant formula, the manufacturer shall:				
(i) Investigate the cause of such variance in the level of any required or added nutrient;				
(ii) Evaluate the significance, if any, of the results for other production aggregates of the same formula that have been released for distribution;				
(iii) Address, as appropriate, all production aggregates of formula released and pending release for distribution that are implicated by the testing results; and				
(iv) Determine whether it is necessary to conduct the testing required by 21 CFR §106.91(b)(1).				
(5) The testing required by 21 CFR §106.91(b)(1) and 21 CFR §106.91(b)(2) is not required to evaluate the level of minerals present in the infant formula.				

AUDIT STANDARDS COMPARISON TO THE INFANT FORMULA REGULATIONS

NOTE: This template does not include certain requirements that may be pertinent to determining compliance with 21 CFR Part 106 and 21 CFR Part 107 (including general requirements, definitions, and certain procedural requirements). "Shall" is used to state mandatory requirements. "Should" is used to state recommended or advisory procedures or to identify recommended equipment. In addition to meeting the applicable requirements of 21 CFR Parts 106 and 107, Infant Formula processors of foods intended for consumption in the U.S. are also required to comply with any other pertinent FDA regulatory requirements outside the elements included in the template (e.g., applicable requirements in 21 CFR part 117 related to current good manufacturing practices and preventive controls, 21 CFR Part 113, 114, and 108, as applicable).

PART 106 — INFANT FORMULA REQUIREMENTS PERTAINING TO CURRENT GOOD MANUFACTURING PRACTICE, QUALITY CONTROL PROCEDURES, QUALITY FACTORS, RECORDS AND REPORTS, AND NOTIFICATIONS	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
(c) All quality control testing shall be conducted using appropriate, scientifically valid test methods.				
(d) A manufacturer shall make and retain quality control records in accordance with §106.100(e)(5)(i).				
§106.92 Audits of quality control procedures.				
(a) A manufacturer of an infant formula, or an agent of such a manufacturer, shall conduct regularly scheduled audits to determine whether the manufacturer has complied with the requirements for quality control procedures that are necessary to ensure that an infant formula provides nutrients in accordance with section 412(b) and (i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350a(b) and (i)) and is manufactured in a manner designed to prevent adulteration of the infant formula under section 412(a)(1) and (a)(3) of the Federal Food, Drug, and Cosmetic Act. Such audits shall be conducted at a frequency that is required to ensure compliance with the requirements for quality control procedures.				
(b) The audits required by 21 CFR §106.92(a) shall be performed by an individual or a team of individuals who, as a result of education, training, or experience, is knowledgeable in all aspects of infant formula production and of the regulations concerning quality control procedures that such individual or team is responsible for auditing. This individual or team of individuals shall have no direct responsibility for the matters that such individual or team is auditing and shall have no direct interest in the outcome of the audit.				
Subpart D—Conduct of Audits				
§106.94 Audit plans and procedures.				

AUDIT STANDARDS COMPARISON TO THE INFANT FORMULA REGULATIONS

NOTE: This template does not include certain requirements that may be pertinent to determining compliance with 21 CFR Part 106 and 21 CFR Part 107 (including general requirements, definitions, and certain procedural requirements). "Shall" is used to state mandatory requirements. "Should" is used to state recommended or advisory procedures or to identify recommended equipment. In addition to meeting the applicable requirements of 21 CFR Parts 106 and 107, Infant Formula processors of foods intended for consumption in the U.S. are also required to comply with any other pertinent FDA regulatory requirements outside the elements included in the template (e.g., applicable requirements in 21 CFR part 117 related to current good manufacturing practices and preventive controls, 21 CFR Part 113, 114, and 108, as applicable).

PART 106 — INFANT FORMULA REQUIREMENTS PERTAINING TO CURRENT GOOD MANUFACTURING PRACTICE, QUALITY CONTROL PROCEDURES, QUALITY FACTORS, RECORDS AND REPORTS, AND NOTIFICATIONS	**Audit Standard Language**	**Analysis of Alignment of Audit Standard**	**Description of Gaps and Actions to Align**	**Additional Comments**
(a) A manufacturer shall develop and follow a written audit plan that is available at the manufacturing facility for Food and Drug Administration inspection.				
(b) The audit plan shall include audit procedures that set out the methods the manufacturer uses to determine whether the facility is operating in accordance with current good manufacturing practice, with the quality control procedures that are necessary to ensure that an infant formula provides nutrients in accordance with sections 412(b) and (i) of the Federal Food, Drug, and Cosmetic Act, and in a manner designed to prevent adulteration of the infant formula.				
(c) The audit procedures shall include:				
(1) An evaluation of the production and in-process control system established under §106.6(b) by:				
(i) Observing the production of infant formula and comparing the observed process to the written production and in-process control plan required under §106.6(b);				
(ii) Reviewing records of the monitoring of points, steps, or stages where control is deemed necessary to prevent adulteration; and				
(iii) Reviewing records of how deviations from any specification at points, steps, or stages where control is deemed necessary to prevent adulteration were handled; and				
(2) A review of a representative sample of all records maintained in accordance with §106.100(e) and (f).				
Subpart E—Quality Factors for Infant Formulas				
§106.96 Requirements for quality factors for infant formulas.				

AUDIT STANDARDS COMPARISON TO THE INFANT FORMULA REGULATIONS

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PART 106 — INFANT FORMULA REQUIREMENTS PERTAINING TO CURRENT GOOD MANUFACTURING PRACTICE, QUALITY CONTROL PROCEDURES, QUALITY FACTORS, RECORDS AND REPORTS, AND NOTIFICATIONS	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
The regulations set forth in this subpart define the minimum requirements for quality factors for infant formulas: (a) An infant formula shall meet the quality factor of normal physical growth.				**For new infant formula, the evidence that the formula meets the quality factors must be submitted to FDA as part of the mandatory pre-market submission as specified in**
(b) A manufacturer of an infant formula that is not an eligible infant formula shall demonstrate that a formula supports normal physical growth in infants when fed as a sole source of nutrition by conducting, in accordance with good clinical practice, an adequate and well-controlled growth monitoring study of the infant formula that:				
(1) Is no less than 15 weeks in duration, enrolling infants no more than 2 weeks old at time of entry into the study				
(2) Includes the collection and maintenance of data on formula intake and anthropometric measures of physical growth, including body weight, recumbent length, head circumference, average daily weight increment, and average daily recumbent length increment;				

AUDIT STANDARDS COMPARISON TO THE INFANT FORMULA REGULATIONS

NOTE: This template does not include certain requirements that may be pertinent to determining compliance with 21 CFR Part 106 and 21 CFR Part 107 (including general requirements, definitions, and certain procedural requirements). "Shall" is used to state mandatory requirements. "Should" is used to state recommended or advisory procedures or to identify recommended equipment. In addition to meeting the applicable requirements of 21 CFR Parts 106 and 107, Infant Formula processors of foods intended for consumption in the U.S. are also required to comply with any other pertinent FDA regulatory requirements outside the elements included in the template (e.g., applicable requirements in 21 CFR part 117 related to current good manufacturing practices and preventive controls, 21 CFR Part 113, 114, and 108, as applicable).

PART 106 — INFANT FORMULA REQUIREMENTS PERTAINING TO CURRENT GOOD MANUFACTURING PRACTICE, QUALITY CONTROL PROCEDURES, QUALITY FACTORS, RECORDS AND REPORTS, AND NOTIFICATIONS	**Audit Standard Language**	**Analysis of Alignment of Audit Standard**	**Description of Gaps and Actions to Align**	**Additional Comments**
(3) Includes anthropometric measurements made at the beginning and end of the study, and at least four additional measurements made at intermediate time points with three of the six total measurements made within the first 4 weeks of the study and three measurements made at approximately 4-week intervals over the remaining 11 weeks of the study;				**106.120(b)(5)(i). Eligible infant formulas (as defined in 106.3) meet the quality factor requirements if they fulfill the criteria described under 106.96(i).**
(4) Compares the anthropometric data for the test group to a concurrent control group or groups at each time point and compares the anthropometric data for each infant (body weight for age, body length for age, head circumference for age, and weight for length) in the test group and the control group to the 2009 CDC growth charts, which are incorporated by reference at §106.160; and				
(5) Compares the data on formula intake of the test group with a concurrent control group or groups and a scientifically appropriate reference.				
(c) The Food and Drug Administration will exempt a manufacturer from the requirements of 21 CFR §106.96((b), if:				

AUDIT STANDARDS COMPARISON TO THE INFANT FORMULA REGULATIONS

NOTE: This template does not include certain requirements that may be pertinent to determining compliance with 21 CFR Part 106 and 21 CFR Part 107 (including general requirements, definitions, and certain procedural requirements). "Shall" is used to state mandatory requirements. "Should" is used to state recommended or advisory procedures or to identify recommended equipment. In addition to meeting the applicable requirements of 21 CFR Parts 106 and 107, Infant Formula processors of foods intended for consumption in the U.S. are also required to comply with any other pertinent FDA regulatory requirements outside the elements included in the template (e.g., applicable requirements in 21 CFR part 117 related to current good manufacturing practices and preventive controls, 21 CFR Part 113, 114, and 108, as applicable).

PART 106 — INFANT FORMULA REQUIREMENTS PERTAINING TO CURRENT GOOD MANUFACTURING PRACTICE, QUALITY CONTROL PROCEDURES, QUALITY FACTORS, RECORDS AND REPORTS, AND NOTIFICATIONS	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
(1) The manufacturer requests an exemption and provides assurances, as required under §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); or				
(2) The manufacturer requests an exemption and provides assurances, as required under §106.121, which demonstrate that:				
(i) 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;				
(ii) The change made by the manufacturer to an existing formula does not affect the ability of the formula to support normal physical growth; or				
(iii) 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.				
(d) A manufacturer of a new infant formula that is not an eligible infant formula shall, in accordance with §106.100(p)(1), make and retain records demonstrating that the formula meets the quality factor of normal physical growth.				
(e) An infant formula shall meet the quality factor of sufficient biological quality of protein.				

AUDIT STANDARDS COMPARISON TO THE INFANT FORMULA REGULATIONS

NOTE: This template does not include certain requirements that may be pertinent to determining compliance with 21 CFR Part 106 and 21 CFR Part 107 (including general requirements, definitions, and certain procedural requirements). "Shall" is used to state mandatory requirements. "Should" is used to state recommended or advisory procedures or to identify recommended equipment. In addition to meeting the applicable requirements of 21 CFR Parts 106 and 107, Infant Formula processors of foods intended for consumption in the U.S. are also required to comply with any other pertinent FDA regulatory requirements outside the elements included in the template (e.g., applicable requirements in 21 CFR part 117 related to current good manufacturing practices and preventive controls, 21 CFR Part 113, 114, and 108, as applicable).

PART 106 — INFANT FORMULA REQUIREMENTS PERTAINING TO CURRENT GOOD MANUFACTURING PRACTICE, QUALITY CONTROL PROCEDURES, QUALITY FACTORS, RECORDS AND REPORTS, AND NOTIFICATIONS	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
(f) A manufacturer of an infant formula that is not an eligible infant formula shall 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 §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(b).				
(g) The Food and Drug Administration will exempt a manufacturer from the requirements of 21 CFR §106.96(f), if:				
(1) The manufacturer requests an exemption and provides assurances as required under §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); or				
(2) The manufacturer requests an exemption and provides assurances, as required under §106.121(h), that demonstrate that the change made by the manufacturer to an existing formula does not affect the bioavailability of the protein.				

AUDIT STANDARDS COMPARISON TO THE INFANT FORMULA REGULATIONS

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PART 106 — INFANT FORMULA REQUIREMENTS PERTAINING TO CURRENT GOOD MANUFACTURING PRACTICE, QUALITY CONTROL PROCEDURES, QUALITY FACTORS, RECORDS AND REPORTS, AND NOTIFICATIONS	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
(3) The manufacturer requests an exemption and provides assurances, as required under §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.				
(h) A manufacturer of a new infant formula that is not an eligible infant formula shall, in accordance with §106.100(q), make and retain records demonstrating that the formula meets the quality factor of sufficient biological quality of protein.				
(i) The following provisions for requirements for quality factors apply only to an "eligible infant formula" as defined in §106.3:				
(1) An eligible infant formula that fulfills one or more of the following criteria meets the quality factor of normal physical growth:				
(i) The scientific evidence on such infant formula meets the requirements of 21 CFR §106.96(b) that apply to infant formula that is not an eligible infant formula;				
(ii) The scientific evidence on such infant formula meets the following provisions:				
(A) The evidence is an adequate and well-controlled growth study, conducted in accordance with good clinical practice, to determine whether an infant formula supports normal physical growth in infants when the formula is fed as the sole source of nutrition;				
(B) The growth study is no less than 4 months in duration, enrolling infants no more than 1 month old at time of entry into the study;				

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(C) The growth study collects from the study subjects data on anthropometric measures of physical growth, including body weight, recumbent length, head circumference, and average daily weight increment, and plots the data on the following charts from "Physical Growth: National Center for Health Statistics Percentiles" for body weight, body length, and head circumference, which are incorporated by reference at §106.160: (1) Figure 1. Length by age percentiles for girls aged birth-36 months (p. 609); (2) Figure 2. Length by age percentiles for boys aged birth-36 months (p. 610); (3) Figure 3. Weight by age percentiles for girls aged birth-36 months (p. 611); (4) Figure 4. Weight by age percentiles for boys aged birth-36 months (p. 612); (5) Figure 5. Head circumference by age percentiles for girls aged birth-36 months (p. 613); (6) Figure 6. Weight by length percentiles for girls aged birth-36 months (p. 613); (7) Figure 7. Head circumference by age percentiles for boys aged birth-36 months (p. 614); and (8) Figure 8. Weight by length percentiles for boys aged birth-36 months (p. 614); and				
(D) The growth study collects anthropometric measurements at the beginning of the growth study, at 2 weeks, at 4 weeks, at least monthly thereafter, and at the conclusion of the study; or				

AUDIT STANDARDS COMPARISON TO THE INFANT FORMULA REGULATIONS

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PART 106 — INFANT FORMULA REQUIREMENTS PERTAINING TO CURRENT GOOD MANUFACTURING PRACTICE, QUALITY CONTROL PROCEDURES, QUALITY FACTORS, RECORDS AND REPORTS, AND NOTIFICATIONS	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
(iii) The scientific evidence on such infant formula otherwise demonstrates that such formula supports normal physical growth.				
(2) An eligible infant formula that fulfills one or more of the following criteria meets the quality factor of sufficient biological quality of the protein:				
(i) The scientific evidence on such infant formula meets the requirements of 21 CFR §106.96(f) that apply to infant formula that is not an eligible infant formula;				
(ii) The scientific evidence on such infant formula is a study that establishes the biological quality of the protein in an infant formula by demonstrating that the protein source supports adequate growth using the Protein Efficiency Ratio (PER) rat bioassay described in sections 45.3.04 and 45.3.05 of the "Official Methods of Analysis of the Association of Official Analytical Chemists," 16th ed., which are incorporated by reference at §106.160; or				
(iii) The scientific evidence on such infant formula otherwise demonstrates that the protein in such infant formula is of sufficient biological quality.				
(3) The manufacturer of an eligible infant formula may, not later than November 12, 2015, submit a petition to the Food and Drug Administration under 21 CFR §10.30 that:				
(i) Demonstrates that such formula fulfills one or more of the criteria in 21 CFR §106.96(i)(1); or				
(ii) Demonstrates that such formula fulfills one or more of the criteria in 21 CFR §106.96(i)(2).				

AUDIT STANDARDS COMPARISON TO THE INFANT FORMULA REGULATIONS

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PART 106 — INFANT FORMULA REQUIREMENTS PERTAINING TO CURRENT GOOD MANUFACTURING PRACTICE, QUALITY CONTROL PROCEDURES, QUALITY FACTORS, RECORDS AND REPORTS, AND NOTIFICATIONS	**Audit Standard Language**	**Analysis of Alignment of Audit Standard**	**Description of Gaps and Actions to Align**	**Additional Comments**
(4) A petition filed under 21 CFR §106.96(i)(3) shall address only one infant formula formulation and shall contain all data and information relied upon by the manufacturer to demonstrate that such formulation fulfills one or more of the criteria in 21 CFR §106.96(i)(1) or in 21 CFR §106.96(i)(2). A manufacturer may combine petitions submitted under 21 CFR §106.96(i)(3)(i) and 21 CFR §106.96(i)(3)(ii) that relate to the same formulation.				
(5) The manufacturer of each eligible infant formula shall make and retain, in accordance with §106.100(p)(2), records to demonstrate that such formula supports normal physical growth in infants when fed as the sole source of nutrition and shall make and retain, in accordance with §106.100(q)(2), records to demonstrate that that the protein in such infant formula is of sufficient biological quality. The records required by this paragraph shall include all relevant scientific data and information and a narrative explanation of why the data and information demonstrate that the formula supports normal physical growth and a narrative explanation of why the data and information demonstrate that the protein in such infant formula is of sufficient biological quality.				
Subpart F—Records and Reports				
§106.100 Records.				
(a) Every manufacturer of infant formula shall maintain the records specified in this regulation in order to permit the Food and Drug Administration to determine whether each manufacturer is in compliance with section 412 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350a)).				

AUDIT STANDARDS COMPARISON TO THE INFANT FORMULA REGULATIONS

NOTE: This template does not include certain requirements that may be pertinent to determining compliance with 21 CFR Part 106 and 21 CFR Part 107 (including general requirements, definitions, and certain procedural requirements). "Shall" is used to state mandatory requirements. "Should" is used to state recommended or advisory procedures or to identify recommended equipment. In addition to meeting the applicable requirements of 21 CFR Parts 106 and 107, Infant Formula processors of foods intended for consumption in the U.S. are also required to comply with any other pertinent FDA regulatory requirements outside the elements included in the template (e.g., applicable requirements in 21 CFR part 117 related to current good manufacturing practices and preventive controls, 21 CFR Part 113, 114, and 108, as applicable).

PART 106 — INFANT FORMULA REQUIREMENTS PERTAINING TO CURRENT GOOD MANUFACTURING PRACTICE, QUALITY CONTROL PROCEDURES, QUALITY FACTORS, RECORDS AND REPORTS, AND NOTIFICATIONS	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
(b) The manufacturer shall maintain all records that pertain to food-packaging materials subject to 21 CFR §174.5 and that bear on whether such materials would cause an infant formula to be adulterated within the meaning of section 402(a)(2)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342(a)(2)(C)).				
(c) The manufacturer shall maintain all records that pertain to nutrient premix testing that it generates or receives. Such records shall include, but are not limited to:				
(1) Any results of testing conducted to ensure that each nutrient premix is in compliance with the premix certificate and guarantee and specifications that have been provided to the manufacturer by the premix supplier, including tests conducted when nutrients exceed their expiration date or shelf life (retest date).				
(2) All certificates and guarantees given by premix suppliers concerning the nutrients required by section 412(i) of the Federal Food, Drug, and Cosmetic Act and 21 CFR §107.100.				
(d) The premix supplier shall maintain the results of all testing conducted to provide all certificates and guarantees concerning nutrient premixes for infant formulas. Such records shall include but are not limited to:				
(1) The results of tests conducted to determine the purity of each nutrient required by section 412(i) of the Federal Food, Drug, and Cosmetic Act or 21 CFR §107.100 and any other nutrient listed in the certificate and guarantee;				
(2) The weight of each nutrient added;				

AUDIT STANDARDS COMPARISON TO THE INFANT FORMULA REGULATIONS

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PART 106 — INFANT FORMULA REQUIREMENTS PERTAINING TO CURRENT GOOD MANUFACTURING PRACTICE, QUALITY CONTROL PROCEDURES, QUALITY FACTORS, RECORDS AND REPORTS, AND NOTIFICATIONS	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
(3) The results of any quantitative tests conducted to determine the amount of each nutrient certified or guaranteed; and				
(4) The results of any quantitative tests conducted to identify the nutrient levels present when nutrient premixes exceed their expiration date or shelf life (retest date).				
(e) For each production aggregate of infant formula, a manufacturer shall prepare and maintain records that include complete information relating to the production and control of the production aggregate. These records shall include:				
(1) The master manufacturing order. The master manufacturing order shall include:				
(i) The significant steps in the production of the production aggregate and the date on which each significant step occurred;				
(ii) For a manufacturing facility that has more than one set of equipment or more than one processing line, the identity of equipment and processing lines for which the manufacturer has identified points, steps, or stages in the production process where control is necessary to prevent adulteration;				
(iii) The identity of each lot of ingredients, containers, and closures used in producing the production aggregate of formula;				
(iv) The amount of each ingredient to be added to the production aggregate of infant formula and a check (verification) that the correct amount was added; and				

AUDIT STANDARDS COMPARISON TO THE INFANT FORMULA REGULATIONS

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PART 106 — INFANT FORMULA REQUIREMENTS PERTAINING TO CURRENT GOOD MANUFACTURING PRACTICE, QUALITY CONTROL PROCEDURES, QUALITY FACTORS, RECORDS AND REPORTS, AND NOTIFICATIONS	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
(v) A copy of each infant formula label used on a finished production aggregate of infant formula and the results of examinations conducted during the finishing operations to provide assurance that the containers and packages have the correct label.				
(2) Any deviations from the master manufacturing order and any corrective actions taken because of the deviations.				
(3) Documentation, in accordance with §106.6(c), of the monitoring at any point, step, or stage in the manufacturer 's production process where control is deemed necessary to prevent adulteration. These records shall include:				
(i) A list of the specifications established at each point, step, or stage in the production process where control is deemed necessary to prevent adulteration, in accordance with §106.6(c)(1), including documentation of the scientific basis for each specification;				
(ii) The actual values obtained during the monitoring operation, any deviations from established specifications, and any corrective actions taken; and				
(iii) Identification of the person monitoring each point, step, or stage in the production process where control is deemed necessary to prevent adulteration.				
(4) The conclusions and followup, along with the identity of the individual qualified by education, training, or experience who investigated:				
(i) Any deviation from the master manufacturing order and any corrective actions taken;				
(ii) A finding that a production aggregate or any of its ingredients failed to meet the infant formula manufacturer's specifications; and				

AUDIT STANDARDS COMPARISON TO THE INFANT FORMULA REGULATIONS

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PART 106 — INFANT FORMULA REQUIREMENTS PERTAINING TO CURRENT GOOD MANUFACTURING PRACTICE, QUALITY CONTROL PROCEDURES, QUALITY FACTORS, RECORDS AND REPORTS, AND NOTIFICATIONS	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
(iii) A failure to meet any specification at any point, step, or stage in the production process where control is deemed necessary to prevent adulteration.				
(5) The results of all testing performed on the production aggregate of infant formula, including testing on the in-process production aggregate, at the final product stage, and on finished product throughout the shelf life of the product. The results recorded shall include:				
(i) The results of all quality control testing conducted in accordance with 21 CFR §106.91(a) and (b) to verify that each nutrient required by 21 CFR §107.100 is present in each production aggregate of infant formula at the level required by 21 CFR §107.100, and that all other nutrients added by the manufacturer are present at the appropriate level. The record of the results of the quality control testing shall include:				
(A) A summary document identifying the stages of the manufacturing process at which the nutrient analysis for each required nutrient is conducted as required under 21 CFR §106.91(a); and				
(B) A summary document on the stability testing program conducted under 21 CFR §106.91(b), including the nutrients tested and the frequency of nutrient testing throughout the shelf life of the product.				
(ii) For powdered infant formula, the results of any testing conducted in accordance with §106.55(c) to verify compliance with the microbiological quality standards in 21 CFR §106.55(e).				
(f) A manufacturer shall make and retain all records described in subparts B and C of 21 CFR part 106, including:				

AUDIT STANDARDS COMPARISON TO THE INFANT FORMULA REGULATIONS

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PART 106 — INFANT FORMULA REQUIREMENTS PERTAINING TO CURRENT GOOD MANUFACTURING PRACTICE, QUALITY CONTROL PROCEDURES, QUALITY FACTORS, RECORDS AND REPORTS, AND NOTIFICATIONS	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
(1) Records, in accordance with 21 CFR §106.20(f)(4), of the frequency and results of testing of the water used in the production of infant formula;				
(2) Records, in accordance with 21 CFR §106.30(d), of accuracy checks of instruments and controls. A certification of accuracy of any known reference standard used and a history of recertification shall be maintained. At a minimum, such records shall specify the instrument or control being checked, the date of the accuracy check, the standard used, the calibration method used, the results found, any actions taken if the instrument is found to be out of calibration, and the initials or name of the individual performing the test. If calibration of an instrument shows that a specification at a point, step, or stage in the production process where control is deemed necessary to prevent adulteration has not been met, a written evaluation of all affected product, and any actions that need to be taken with respect to that product, shall be made.				
(3) Records, in accordance with 21 CFR §106.30(e)(3)(iii).				
(4) Records, in accordance with 21 CFR §106.30(f), on equipment cleaning, sanitizing, and maintenance that show the date and time of such cleaning, sanitizing, and maintenance and the production aggregate number of each infant formula processed between equipment startup and shutdown for cleaning, sanitizing, and maintenance. The person performing and checking the cleaning, sanitizing, and maintenance shall date and sign or initial the record indicating that the work was performed.				
(5) Records, in accordance with 21 CFR §106.35(c), on all mechanical and electronic equipment used in the production or quality control of infant formula. These records shall include:				

AUDIT STANDARDS COMPARISON TO THE INFANT FORMULA REGULATIONS

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PART 106 — INFANT FORMULA REQUIREMENTS PERTAINING TO CURRENT GOOD MANUFACTURING PRACTICE, QUALITY CONTROL PROCEDURES, QUALITY FACTORS, RECORDS AND REPORTS, AND NOTIFICATIONS	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
(i) A list of all systems used with a description of the computer files and the defined capabilities and inherent limitations of each system;				
(ii) A copy of all software used;				
(iii) Records that document installation, calibration, testing or validation, and maintenance of the systems used;				
(iv) A list of all persons authorized to create or modify software;				
(v) Records that document modifications to software, including the identity of the person who modified the software;				
(vi) Records that document retesting or revalidation of modified systems; and				
(vii) A backup file of data entered into a computer or related system. The backup file shall consist of a hard copy or alternative system, such as duplicate electronic records, tapes, or microfilm, designed to ensure that backup data are exact and complete, and that they are secure from alteration, inadvertent erasures, or loss.				
(6) Records, in accordance with 21 CFR §106.40(g), on ingredients, containers, and closures used in the manufacture of infant formula. These records shall include:				
(i) The identity and quantity of each lot of ingredients, containers, and closures;				
(ii) The name of the supplier;				
(iii) The supplier's lot numbers;				
(iv) The name and location of the manufacturer of the ingredient, container, or closure, if different from the supplier;				
(v) The date of receipt;				
(vi) The receiving code as specified; and				

AUDIT STANDARDS COMPARISON TO THE INFANT FORMULA REGULATIONS

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PART 106 — INFANT FORMULA REQUIREMENTS PERTAINING TO CURRENT GOOD MANUFACTURING PRACTICE, QUALITY CONTROL PROCEDURES, QUALITY FACTORS, RECORDS AND REPORTS, AND NOTIFICATIONS	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
(vii) The results of any test or examination (including retesting and reexamination) performed on the ingredients, containers, or closures and the conclusions derived there from and the disposition of all ingredients, containers, or closures.				
(7) A full description of the methodology used to test powdered infant formula to verify compliance with the microbiological quality standards of 21 CFR §106.55(c) and the methodology used to do quality control testing, in accordance with 21 CFR §106.91(a).				
(g) A manufacturer shall maintain all records pertaining to distribution of the infant formula, including records that show that formula produced for export only is exported. Such records shall include all information and data necessary to effect and monitor recalls of the manufacturer's infant formula products in accordance with subpart E of 21 CFR part 107.				
(h) The manufacturer shall maintain all records pertaining to the microbiological quality and purity of raw materials and finished powdered infant formula.				
(j) The manufacturer shall make and retain records pertaining to regularly scheduled audits, including the audit plans and procedures, the findings of the audit, and a listing of any changes made in response to these findings. The manufacturer shall make readily available for authorized inspection the audit plans and procedures and a statement of assurance that the regularly scheduled audits are being conducted. The findings of the audit and any changes made in response to these findings shall be maintained for the time period required under 21 CFR §106.100(n), but need not be made available to the Food and Drug Administration.				

AUDIT STANDARDS COMPARISON TO THE INFANT FORMULA REGULATIONS

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PART 106 — INFANT FORMULA REQUIREMENTS PERTAINING TO CURRENT GOOD MANUFACTURING PRACTICE, QUALITY CONTROL PROCEDURES, QUALITY FACTORS, RECORDS AND REPORTS, AND NOTIFICATIONS	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
(k) The manufacturer shall maintain procedures describing how all written and oral complaints regarding infant formula will be handled. The manufacturer shall follow these procedures and shall include in them provisions for the review of any complaint involving an infant formula and for determining the need for an investigation of the possible existence of a hazard to health.				
(1) For purposes of 21 CFR §106.100, every manufacturer shall interpret a "complaint" as any communication that contains any allegation, written or oral, expressing dissatisfaction with a product for any reason, including concerns about the possible existence of a hazard to health and about appearance, taste, odor, and quality. Correspondence about prices, package size or shape, or other matters that could not possibly reveal the existence of a hazard to health shall not, for compliance purposes, be considered a complaint and therefore need not be made available to a Food and Drug Administration investigator.				
(2) When a complaint shows that a hazard to health possibly exists, the manufacturer shall conduct an investigation into the validity of the complaint. Where such an investigation is conducted, the manufacturer shall include in its file on the complaint the determination as to whether a hazard to health exists and the basis for that determination. No investigation is necessary when the manufacturer determines that there is no possibility of a hazard to health. When no investigation is necessary, the manufacturer shall include in the record the reason that an investigation was found to be unnecessary and the name of the responsible person making that determination.				

AUDIT STANDARDS COMPARISON TO THE INFANT FORMULA REGULATIONS

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PART 106 — INFANT FORMULA REQUIREMENTS PERTAINING TO CURRENT GOOD MANUFACTURING PRACTICE, QUALITY CONTROL PROCEDURES, QUALITY FACTORS, RECORDS AND REPORTS, AND NOTIFICATIONS	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
(3) When there is a reasonable possibility of a causal relationship between the consumption of an infant formula and an infant's death, the manufacturer shall, within 15 days of receiving such information, conduct an investigation and notify the Agency as required in §106.150.				
(4) The manufacturer shall maintain in designated files all records pertaining to the complaints it receives. The manufacturer shall separate the files into two classes:				
(i) Those complaints that allege that the infant became ill from consuming the product or required treatment by a physician or health care provider and				
(ii) Those complaints that may involve a possible existence of a hazard to health but do not refer to an infant becoming ill or the need for treatment by physician or a health care provider.				

AUDIT STANDARDS COMPARISON TO THE INFANT FORMULA REGULATIONS

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PART 106 — INFANT FORMULA REQUIREMENTS PERTAINING TO CURRENT GOOD MANUFACTURING PRACTICE, QUALITY CONTROL PROCEDURES, QUALITY FACTORS, RECORDS AND REPORTS, AND NOTIFICATIONS	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
(5) The manufacturer shall include in a complaint file the following information concerning the complaint: (i) The name of the infant formula; (ii) The production aggregate number; (iii) The name of complainant; (iv) A copy of the complaint or a memo of the telephone conversation or meeting and all correspondence with the complainant; (v) By reference or copy, all the associated manufacturing records and complaint investigation records needed to evaluate the complaint. When copies of such records are not maintained in the complaint file, they must be available within 24 hours when requested by a Food and Drug Administration official. (vi) All actions taken to followup on the complaint; and (vii) All findings and evaluations of the complaint.				
(6) The manufacturer should maintain the files regarding infant formula complaints at the establishment where the infant formula was manufactured, processed, or packed. When the manufacturer wishes to maintain all consumer complaints for the entire firm at one location other than at the facility where an infant formula was manufactured, processed, or packed, the manufacturer may do so as long as all records required by 21 CFR §106.100 are available within 24 hours of request for inspection at that facility. However, all records of consumer complaints, including summaries, any reports, and any files, maintained at the manufacturing facility or at any other facility shall be made available to investigators for review and copying upon request.				

AUDIT STANDARDS COMPARISON TO THE INFANT FORMULA REGULATIONS

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PART 106 — INFANT FORMULA REQUIREMENTS PERTAINING TO CURRENT GOOD MANUFACTURING PRACTICE, QUALITY CONTROL PROCEDURES, QUALITY FACTORS, RECORDS AND REPORTS, AND NOTIFICATIONS	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
(l) The manufacturer shall make readily available for authorized inspection all records required under 21 CFR part 106 or copies of such records. Records shall be available at any reasonable time at the establishment where the activities described in such records occurred. (Infant formula complaint files may be maintained at one facility, as provided in 21 CFR §106.100(k)(6), if all required records are readily available at that facility.) These records or copies thereof shall be subject to photocopying or other means of reproduction as part of such inspection. Records that can be immediately retrieved from another location by electronic means shall be considered as meeting the requirements of this paragraph.				
(m) A manufacturer shall maintain all records required under 21 CFR part 106 in a manner that ensures that both the manufacturer and the Food and Drug Administration can be provided with access to such records within 24 hours. The manufacturer may maintain the records required under 21 CFR part 106 as original records, as true copies such as photocopies, microfilm, microfiche, or other accurate reproductions of the original records, or as electronic records. Where reduction techniques, such as microfilming, are used, suitable reader and photocopying equipment shall be readily available. All electronic records maintained under this part shall comply with 21 CFR part 11.				
(n) Production control, product testing, testing results, complaints, and distribution records necessary to verify compliance with 21 CFR parts 106, 107, 109, 110, 113, and 117, or with other appropriate regulations, shall be retained for 1 year after the expiration of the shelf life of the infant formula or 3 years from the date of manufacture, whichever is greater.				

AUDIT STANDARDS COMPARISON TO THE INFANT FORMULA REGULATIONS

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PART 106 — INFANT FORMULA REQUIREMENTS PERTAINING TO CURRENT GOOD MANUFACTURING PRACTICE, QUALITY CONTROL PROCEDURES, QUALITY FACTORS, RECORDS AND REPORTS, AND NOTIFICATIONS	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
(o) The manufacturer shall maintain quality control records that contain sufficient information to permit a public health evaluation of any production aggregate of infant formula.				
(p) A manufacturer shall make and retain records that demonstrate that the formula meets the quality factor of normal physical growth.				
(1) For an infant formula that is not an eligible infant formula, in accordance with §106.96(d), these records shall include:				
(i) Records demonstrating compliance with the requirements in §106.96(b), including records made in compliance with §106.121; or				
(ii) Records demonstrating satisfaction of an applicable exemption under §106.96(c), including records made in compliance with §106.121.				
(2) For an eligible infant formula, in accordance with §106.96(i)(5), these records shall include records demonstrating that the formula fulfills one or more of the criteria listed in §106.96(i)(1).				
(q) A manufacturer shall make and retain records that demonstrate that a formula meets the quality factor of sufficient biological quality of protein.				
(1) For an infant formula that is not an eligible infant formula, in accordance with §106.96(h), these records shall include:				
(i) Records demonstrating compliance with the requirements in §106.96(f), including records made in compliance with §106.121; or				
(ii) Records demonstrating satisfaction of an applicable exemption under §106.96(g), including records made in compliance with §106.121.				

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(2) For an eligible infant formula, in accordance with §106.96(i)(5), these records shall include records demonstrating that the formula fulfills one or more of the criteria listed in §106.96(i)(2).				
Subpart G—Registration, Submission, and Notification Requirements				
§106.110 New infant formula registration.				
(a) Before a new infant formula may be introduced or delivered for introduction into interstate commerce, including a new infant formula for export only, the manufacturer of the formula shall register with the Food and Drug Administration, Center for Food Safety and Applied Nutrition, Office of Nutrition, Labeling, and Dietary Supplements, Infant Formula and Medical Foods Staff (HFS-850), 5001 Campus Dr., College Park, MD 20740-3835.				
(b) The new infant formula registration shall include: (1) The name of the new infant formula; (2) The name of the manufacturer; (3) The street address of the place of business of the manufacturer; and (4) The name and street address of each establishment at which the manufacturer intends to manufacture such new infant formula.				
§106.120 New infant formula submission.[1]				

[1] FDA assesses the content of the pre-market submission as described in §106.120(b) - §106.120(f) and in §106.121. The provisions are available in the appendix at the end of the audit template for reference.

AUDIT STANDARDS COMPARISON TO THE INFANT FORMULA REGULATIONS

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(a) At least 90 days before a new infant formula is introduced or delivered for introduction into interstate commerce, a manufacturer shall submit notice of its intent to do so to the Food and Drug Administration at the address given in §106.110(a). An original and two paper copies of such notice of intent shall be submitted, unless the notice is submitted in conformance with 21 CFR part 11, in which case a single copy shall be sufficient.				
(g) Submissions relating to exempt infant formulas are subject to the provisions of §107.50 of 21 CFR part 107.				
§106.130 Verification submission.				
(a) A manufacturer shall, 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 §106.120(c)), verify in a written submission to the Food and Drug Administration at the address given in §106.110(a) that the infant formula complies with the requirements of the Federal Food, Drug, and Cosmetic Act and is not adulterated.				
(b) The verification submission shall include the following information:				
(1) The name of the new infant formula; the filing date for the new infant formula submission, in accordance with §106.120, for the subject formula; and the identification number assigned by the Agency to the new infant formula submission:				

AUDIT STANDARDS COMPARISON TO THE INFANT FORMULA REGULATIONS

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PART 106 — INFANT FORMULA REQUIREMENTS PERTAINING TO CURRENT GOOD MANUFACTURING PRACTICE, QUALITY CONTROL PROCEDURES, QUALITY FACTORS, RECORDS AND REPORTS, AND NOTIFICATIONS	**Audit Standard Language**	**Analysis of Alignment of Audit Standard**	**Description of Gaps and Actions to Align**	**Additional Comments**
(2) A statement that 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;				
(3) 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 product stage.				
(4) A certification that the manufacturer has established current good manufacturing practices, including quality control procedures and in-process controls, and testing required by current good manufacturing practice, designed to prevent adulteration of this formula in accordance with subparts B and C of 21 CFR part 106.				
(c) The submission shall not constitute written verification under section 412(d)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350a(d)(2)) when any data prescribed in 21 CFR §106.130(b) are lacking or are not set forth so as to be readily understood. In such circumstances, the Agency will notify the manufacturer that the notice is not adequate.				
§106.140 Submission concerning a change in infant formula that may adulterate the product.				

AUDIT STANDARDS COMPARISON TO THE INFANT FORMULA REGULATIONS

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(a) When a manufacturer makes a change in the formulation or processing of the formula that may affect whether the formula is adulterated under section 412(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350a(a)), the manufacturer shall, before the first processing of such formula, make a submission to the Food and Drug Administration at the address given in §106.110(a). An original and two copies shall be submitted.				**Submission to FDA is required prior to the first processing of such formula. A response letter from FDA is not required prior to marketing.**
(b) The submission shall include:				
(1) The name and physical form of the infant formula (i.e., powder, ready-to-feed, or concentrate);				
(2)(i) An explanation of why the change in formulation or processing may affect whether the formula is adulterated; and				
(ii) What steps will be taken to ensure that, before the formula is introduced into interstate commerce, the formula will not be adulterated; and				
(3) A statement that the submission complies with §106.120(b)(3), (b)(4), (b)(5), and (b)(6). When appropriate, a statement to the effect that the information required by §106.120(b)(3), (b)(4), (b)(5), or (b)(6) has been provided to the Agency previously and has not been affected by the changes that are the subject of the current submission, together with the identification number assigned by the Agency to the relevant infant formula submission, may be provided in lieu of such statement.				

AUDIT STANDARDS COMPARISON TO THE INFANT FORMULA REGULATIONS

NOTE: This template does not include certain requirements that may be pertinent to determining compliance with 21 CFR Part 106 and 21 CFR Part 107 (including general requirements, definitions, and certain procedural requirements). "Shall" is used to state mandatory requirements. "Should" is used to state recommended or advisory procedures or to identify recommended equipment. In addition to meeting the applicable requirements of 21 CFR Parts 106 and 107, Infant Formula processors of foods intended for consumption in the U.S. are also required to comply with any other pertinent FDA regulatory requirements outside the elements included in the template (e.g., applicable requirements in 21 CFR part 117 related to current good manufacturing practices and preventive controls, 21 CFR Part 113, 114, and 108, as applicable).

PART 106 — INFANT FORMULA REQUIREMENTS PERTAINING TO CURRENT GOOD MANUFACTURING PRACTICE, QUALITY CONTROL PROCEDURES, QUALITY FACTORS, RECORDS AND REPORTS, AND NOTIFICATIONS	**Audit Standard Language**	**Analysis of Alignment of Audit Standard**	**Description of Gaps and Actions to Align**	**Additional Comments**
(c) The submission shall not constitute notice under section 412 of the Federal Food, Drug, and Cosmetic Act unless it complies fully with 21 CFR §106.140(b), and the information that it contains is set forth in a manner that is readily understandable. The Agency will notify the manufacturer if the notice is not adequate because it does not meet the requirements of section 412(d)(3) of the Federal Food, Drug, and Cosmetic Act.				
§106.150 Notification of an adulterated or misbranded infant formula.				
(a) A manufacturer shall promptly notify the Food and Drug Administration in accordance with 21 CFR §106.150(b) when the manufacturer has knowledge (that is, actual knowledge that the manufacturer had, or the knowledge which a reasonable person would have had under like circumstances or which would have been obtained upon the exercise of due care) that reasonably supports the conclusion that an infant formula that has been processed by the manufacturer and that has left an establishment subject to the control of the manufacturer:				
(1) May not provide the nutrients required by section 412(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C 350d(i)) or by regulations issued under section 412(i)(2); or				
(2) May be otherwise adulterated or misbranded.				

AUDIT STANDARDS COMPARISON TO THE INFANT FORMULA REGULATIONS

NOTE: This template does not include certain requirements that may be pertinent to determining compliance with 21 CFR Part 106 and 21 CFR Part 107 (including general requirements, definitions, and certain procedural requirements). "Shall" is used to state mandatory requirements. "Should" is used to state recommended or advisory procedures or to identify recommended equipment. In addition to meeting the applicable requirements of 21 CFR Parts 106 and 107, Infant Formula processors of foods intended for consumption in the U.S. are also required to comply with any other pertinent FDA regulatory requirements outside the elements included in the template (e.g., applicable requirements in 21 CFR part 117 related to current good manufacturing practices and preventive controls, 21 CFR Part 113, 114, and 108, as applicable).

PART 106 — INFANT FORMULA REQUIREMENTS PERTAINING TO CURRENT GOOD MANUFACTURING PRACTICE, QUALITY CONTROL PROCEDURES, QUALITY FACTORS, RECORDS AND REPORTS, AND NOTIFICATIONS	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
(b) The notification made according to 21 CFR §106.150(a) shall be made by telephone, to the Director of the appropriate Food and Drug Administration district office. After normal business hours (8 a.m. to 4:30 p.m.), the Food and Drug Administration's emergency number, 1-866-300-4374 shall be used. The manufacturer shall promptly send written confirmation of the notification to the Food and Drug Administration, Center for Food Safety and Applied Nutrition, Office of Compliance, Division of Enforcement (HFS-605), Recall Coordinator, 5001 Campus Dr., College Park, MD 20740, and to the appropriate Food and Drug Administration district office.				

AUDIT STANDARDS COMPARISON TO THE INFANT FORMULA REGULATIONS

NOTE: This template does not include certain requirements that may be pertinent to determining compliance with 21 CFR Part 106 and 21 CFR Part 107 (including general requirements, definitions, and certain procedural requirements). "Shall" is used to state mandatory requirements. "Should" is used to state recommended or advisory procedures or to identify recommended equipment. In addition to meeting the applicable requirements of 21 CFR Parts 106 and 107, Infant Formula processors of foods intended for consumption in the U.S. are also required to comply with any other pertinent FDA regulatory requirements outside the elements included in the template (e.g., applicable requirements in 21 CFR part 117 related to current good manufacturing practices and preventive controls, 21 CFR Part 113, 114, and 108, as applicable).

PART 107 — INFANT FORMULA	**Audit Standard Language**	**Analysis of Alignment of Audit Standard**	**Description of Gaps and Actions to Align**	**Additional Comments**
Subpart B—Labeling				
§107.10 Nutrient information.				
(a) The labeling of infant formulas, as defined in section 201(z) of the Federal Food, Drug, and Cosmetic Act, shall bear in the order given, in the units specified, and in tabular format, the following information regarding the product as prepared in accordance with label directions for infant consumption:				
(1) A statement of the number of fluid ounces supplying 100 kilocalories (in case of food label statements, a kilocalorie is represented by the word "Calorie"); and				

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(2) A statement of the amount, supplied by 100 kilocalories, of each of the following nutrients and of any other nutrient added by the manufacturer:

Nutrients	Unit of measurement
Protein	Grams
Fat	Do.
Carbohydrate	Do.
Water	Do.
Linoleic acid	Milligrams
Vitamins	
Vitamin A	International Units
Vitamin D	Do.
Vitamin E	Do.
Vitamin K	Micrograms
Thiamine (Vitamin B_1)	Do.
Riboflavin (Vitamin B_2)	Do.
Vitamin B_6	Do.
Vitamin B_{12}	Do.

NOTE: This template does not include certain requirements that may be pertinent to determining compliance with 21 CFR Part 106 and 21 CFR Part 107 (including general requirements, definitions, and certain procedural requirements). "Shall" is used to state mandatory requirements. "Should" is used to state recommended or advisory procedures or to identify recommended equipment. In addition to meeting the applicable requirements of 21 CFR Parts 106 and 107, Infant Formula processors of foods intended for consumption in the U.S. are also required to comply with any other pertinent FDA regulatory requirements outside the elements included in the template (e.g., applicable requirements in 21 CFR part 117 related to current good manufacturing practices and preventive controls, 21 CFR Part 113, 114, and 108, as applicable).

Niacin	Do.				
Folic acid (Folacin)	Do.				
Pantothenic acid	Do.				
Biotin	Do.				
Vitamin C (Ascorbic acid)	Milligrams				
Choline	Do.				
Inositol	Do.				
Minerals					
Calcium	Milligrams				
Phosphorus	Do.				
Magnesium	Do.				
Iron	Do.				
Zinc	Do.				
Manganese	Micrograms				
Copper	Do.				
Iodine	Do.				
Selenium	Do.				
Sodium	Milligrams				

AUDIT STANDARDS COMPARISON TO THE INFANT FORMULA REGULATIONS

NOTE: This template does not include certain requirements that may be pertinent to determining compliance with 21 CFR Part 106 and 21 CFR Part 107 (including general requirements, definitions, and certain procedural requirements). "Shall" is used to state mandatory requirements. "Should" is used to state recommended or advisory procedures or to identify recommended equipment. In addition to meeting the applicable requirements of 21 CFR Parts 106 and 107, Infant Formula processors of foods intended for consumption in the U.S. are also required to comply with any other pertinent FDA regulatory requirements outside the elements included in the template (e.g., applicable requirements in 21 CFR part 117 related to current good manufacturing practices and preventive controls, 21 CFR Part 113, 114, and 108, as applicable).

PART 107 — INFANT FORMULA		Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
Potassium	Do.				
Chloride	Do.				
(b) In addition the following apply:					
(1) Vitamin A content may also be declared on the label in units of microgram retinol equivalents, vitamin D content in units of micrograms cholecalciferol, vitamin E content in units of milligram alpha-tocopherol equivalents, and sodium, potassium, and chloride content in units of millimoles, micromoles, or milliequivalents. When these declarations are made they shall appear in parentheses immediately following the declarations in International Units for vitamins A, D, and E, and immediately following the declarations in milligrams for sodium, potassium, and chloride.					
(2) Biotin, choline, and inositol content shall be declared except when they are not added to milk-based infant formulas.					
(3) Each of the listed nutrients, and the caloric density, may also be declared on the label on other bases, such as per 100 milliliters or per liter, as prepared for infant consumption.					
(4) One of the following statements shall appear on the principal display panel, as appropriate:					
(i) The statement "Infant Formula With Iron", or a similar statement, if the product contains 1 milligram or more of iron in a quantity of product that supplies 100 kilocalories when prepared in accordance with label directions for infant consumption.					

AUDIT STANDARDS COMPARISON TO THE INFANT FORMULA REGULATIONS

NOTE: This template does not include certain requirements that may be pertinent to determining compliance with 21 CFR Part 106 and 21 CFR Part 107 (including general requirements, definitions, and certain procedural requirements). "Shall" is used to state mandatory requirements. "Should" is used to state recommended or advisory procedures or to identify recommended equipment. In addition to meeting the applicable requirements of 21 CFR Parts 106 and 107, Infant Formula processors of foods intended for consumption in the U.S. are also required to comply with any other pertinent FDA regulatory requirements outside the elements included in the template (e.g., applicable requirements in 21 CFR part 117 related to current good manufacturing practices and preventive controls, 21 CFR Part 113, 114, and 108, as applicable).

PART 107 — INFANT FORMULA	**Audit Standard Language**	**Analysis of Alignment of Audit Standard**	**Description of Gaps and Actions to Align**	**Additional Comments**
(ii) The statement "Additional Iron May Be Necessary", or a similar statement, if the product contains less than 1 milligram of iron in a quantity of product that supplies 100 kilocalories when prepared in accordance with label directions for infant consumption.				
(5) Any additional vitamin may be declared at the bottom of the vitamin list and any additional minerals may be declared between iodine and sodium, provided that any additionally declared nutrient:				
(i) Has been identified as essential by the Food and Nutrition Board of the Institute of Medicine through its development of a Dietary Reference Intake, or has been identified as essential by the Food and Drug Administration through a FEDERAL REGISTER publication; and				
(ii) Is provided at a level considered in these publications as having biological significance, when these levels are known.				
§107.20 Directions for use.				
In addition to the applicable labeling requirements in 21 CFR parts 101 and 105, the product label shall bear:				
(a) Under the heading "Directions For Preparation and Use", directions for:				
(1) Storage of infant formula before and after the container has been opened, including a statement indicating that prolonged storage at excessive temperatures should be avoided;				
(2) Agitating liquid infant formula before opening the container, such as "Shake Well Before Opening";				
(3) "Sterilization" of water, bottle, and nipples when necessary for preparing infant formula for use;				

AUDIT STANDARDS COMPARISON TO THE INFANT FORMULA REGULATIONS

NOTE: This template does not include certain requirements that may be pertinent to determining compliance with 21 CFR Part 106 and 21 CFR Part 107 (including general requirements, definitions, and certain procedural requirements). "Shall" is used to state mandatory requirements. "Should" is used to state recommended or advisory procedures or to identify recommended equipment. In addition to meeting the applicable requirements of 21 CFR Parts 106 and 107, Infant Formula processors of foods intended for consumption in the U.S. are also required to comply with any other pertinent FDA regulatory requirements outside the elements included in the template (e.g., applicable requirements in 21 CFR part 117 related to current good manufacturing practices and preventive controls, 21 CFR Part 113, 114, and 108, as applicable).

PART 107 — INFANT FORMULA	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
(4) Dilution of infant formula, when appropriate. Directions for powdered infant formula shall contain the weight and volume of powdered formula to be reconstituted.				
(b) In close proximity to the "Directions for Preparation and Use" a pictogram depicting the major steps for preparation of that infant formula, such as (for a concentrated formula): https://www.ecfr.gov/graphics/pdfs/er01ja93.366.pdf				
(c) A "Use by ___" date, the blank to be filled in with the month and year selected by the manufacturer, packer, or distributor of the infant formula on the basis of tests or other information showing that the infant formula, until that date, under the conditions of handling, storage, preparation, and use prescribed by label directions, will: (1) when consumed, contain not less than the quantity of each nutrient, as set forth on its label; and (2) otherwise be of an acceptable quality (e.g., pass through an ordinary bottle nipple).				
(d) The statement "Add Water" or "Do Not Add Water", as appropriate, to appear on the principal display panel of concentrated or ready-to-feed infant formulas. In close proximity to the statement "Add Water", a symbol such as https://www.ecfr.gov/graphics/pdfs/ec01mr93.000.pdf if the addition of water is necessary. The symbol shall be placed on a white background encircled by a dark border.				
(e) A warning statement beneath or in close proximity to the "Directions For Preparation and Use" that cautions against improper preparation or use of an infant formula, such as "THE HEALTH OF YOUR INFANT DEPENDS ON CAREFULLY FOLLOWING THE DIRECTIONS FOR PREPARATION AND USE".				

NOTE: This template does not include certain requirements that may be pertinent to determining compliance with 21 CFR Part 106 and 21 CFR Part 107 (including general requirements, definitions, and certain procedural requirements). "Shall" is used to state mandatory requirements. "Should" is used to state recommended or advisory procedures or to identify recommended equipment. In addition to meeting the applicable requirements of 21 CFR Parts 106 and 107, Infant Formula processors of foods intended for consumption in the U.S. are also required to comply with any other pertinent FDA regulatory requirements outside the elements included in the template (e.g., applicable requirements in 21 CFR part 117 related to current good manufacturing practices and preventive controls, 21 CFR Part 113, 114, and 108, as applicable).

PART 107 — INFANT FORMULA	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
(f) A statement indicating that parents should consult their physicians about the use of infant formulas, such as "USE AS DIRECTED BY A PHYSICIAN".				
§107.30 Exemptions.				
When containers of ready-to-feed infant formula, to be sold at the retail level, are contained within a multiunit package, the labels of the individual containers shall contain all of the label information required by section 403 of the Federal Food, Drug, and Cosmetic Act (the act), §§107.10 and 107.20, and all appropriate sections of part 101 of this chapter, except that the labels of the individual containers contained within the outer package shall be exempt from compliance with the requirements of section 403 (e)(1) and (i)(2) of the act; and §§107.10 (a) and (b)(2) and 107.20 (b), (e), and (f), provided that (a) the multiunit package meets all the requirements of this part; (b) individual containers are securely enclosed within and are not intended to be separated from the retail package under conditions of retail sale; and (c) the label on each individual container includes the statement "This Unit Not Intended For Individual Sale" in type size not less than one-sixteenth inch in height. The word "Retail" may be used in lieu of or immediately following the word "Individual" in the statement.				
Subpart C – Exempt Infant Formulas				
§107.50 Terms and conditions.				

AUDIT STANDARDS COMPARISON TO THE INFANT FORMULA REGULATIONS

NOTE: This template does not include certain requirements that may be pertinent to determining compliance with 21 CFR Part 106 and 21 CFR Part 107 (including general requirements, definitions, and certain procedural requirements). "Shall" is used to state mandatory requirements. "Should" is used to state recommended or advisory procedures or to identify recommended equipment. In addition to meeting the applicable requirements of 21 CFR Parts 106 and 107, Infant Formula processors of foods intended for consumption in the U.S. are also required to comply with any other pertinent FDA regulatory requirements outside the elements included in the template (e.g., applicable requirements in 21 CFR part 117 related to current good manufacturing practices and preventive controls, 21 CFR Part 113, 114, and 108, as applicable).

PART 107 — INFANT FORMULA	**Audit Standard Language**	**Analysis of Alignment of Audit Standard**	**Description of Gaps and Actions to Align**	**Additional Comments**
(a) *Terms and conditions.* Section 412(f)(1) of the FD&C Act exempts from the requirements of section 412(a), (b), and (c)(1)(A) of the FD&C Act infant formulas that are represented and labeled for use by an infant who has an inborn error of metabolism or low birth weight or who otherwise has an unusual medical or dietary problem, if such formulas comply with regulations prescribed by the Secretary. The regulations in this subpart establish the terms and conditions that a manufacturer must meet with respect to such infant formulas.				
(b) *Infant formulas generally available at the retail level.* (1) These exempt infant formulas can generally be purchased from retail store shelves that are readily available to the public. Such formulas are also typically represented and labeled for use to provide dietary management for diseases or conditions that are not clinically serious or life-threatening, even though such formulas may also be represented and labeled for use in clinically serious or life-threatening disorders.				
(2) Except as provided in 21 CFR §107.50(b)(4) and (5), an infant formula manufacturer shall, with respect to each formula covered by this paragraph, comply with the nutrient requirements of section 412(g) of the FD&C Act or of regulations promulgated under section 412(a)(2) of the FD&C Act, the quality control procedure requirements of 21 CFR part 106, and the labeling requirements of subpart B of 21 CFR part 107.				

AUDIT STANDARDS COMPARISON TO THE INFANT FORMULA REGULATIONS

NOTE: This template does not include certain requirements that may be pertinent to determining compliance with 21 CFR Part 106 and 21 CFR Part 107 (including general requirements, definitions, and certain procedural requirements). "Shall" is used to state mandatory requirements. "Should" is used to state recommended or advisory procedures or to identify recommended equipment. In addition to meeting the applicable requirements of 21 CFR Parts 106 and 107, Infant Formula processors of foods intended for consumption in the U.S. are also required to comply with any other pertinent FDA regulatory requirements outside the elements included in the template (e.g., applicable requirements in 21 CFR part 117 related to current good manufacturing practices and preventive controls, 21 CFR Part 113, 114, and 108, as applicable).

PART 107 — INFANT FORMULA	**Audit Standard Language**	**Analysis of Alignment of Audit Standard**	**Description of Gaps and Actions to Align**	**Additional Comments**
(3) To retain the exempt status of an infant formula covered by this paragraph, the manufacturer shall submit to the Food and Drug Administration (FDA), at the address specified in 21 CFR §107.50(e)(1), on or before May 21, 1986, or on or before the 90th day before the first processing of the infant formula for commercial or charitable distribution, whichever occurs later, the label and other labeling of the infant formula, a complete quantitative formulation for the infant formula, and a detailed description of the medical conditions for which the infant formula is represented. FDA will review the information under 21 CFR §107.50(d).				
(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 at the address specified in 21 CFR §107.50(e)(1), before the first processing of the infant formula, the label and other labeling of the infant formula, a complete quantitative formulation for the infant formula, a detailed description of the reformulation and the rationale for the reformulation, a complete description of the change in processing, and a detailed description of the medical conditions for which the infant formula is represented. FDA will review that information under 21 CFR §107.50(d).				**Submission to FDA is required prior to the first processing of such formula. A response letter from FDAis not required prior to marketing.**

NOTE: This template does not include certain requirements that may be pertinent to determining compliance with 21 CFR Part 106 and 21 CFR Part 107 (including general requirements, definitions, and certain procedural requirements). "Shall" is used to state mandatory requirements. "Should" is used to state recommended or advisory procedures or to identify recommended equipment. In addition to meeting the applicable requirements of 21 CFR Parts 106 and 107, Infant Formula processors of foods intended for consumption in the U.S. are also required to comply with any other pertinent FDA regulatory requirements outside the elements included in the template (e.g., applicable requirements in 21 CFR part 117 related to current good manufacturing practices and preventive controls, 21 CFR Part 113, 114, and 108, as applicable).

PART 107 — INFANT FORMULA	**Audit Standard Language**	**Analysis of Alignment of Audit Standard**	**Description of Gaps and Actions to Align**	**Additional Comments**
(5) A manufacturer may deviate from the requirements of 21 CFR §107.50(b)(2) only with respect to those specific requirements for which it submits to FDA, at the address specified in 21 CFR §107.50(e)(1), the medical, nutritional, scientific, or technological rationale (including any appropriate animal or human clinical studies). FDA will review that information under 21 CFR §107.50(d).				
(c) *Infant formulas not generally available at the retail level.* (1) These exempt infant formulas are not generally found on retail shelves for general consumer purchase. Such formulas typically are prescribed by a physician, and must be requested from a pharmacist or are distributed directly to institutions such as hospitals, clinics, and State or Federal agencies. Such formulas are also generally represented and labeled solely to provide dietary management for specific diseases or conditions that are clinically serious or life-threatening and generally are required for prolonged periods of time. Exempt infant formulas distributed directly to institutions such as hospitals, clinics, and State or Federal agencies that are of the same formulation as those generally available at the retail level are subject to the requirements of 21 CFR §107.50(b) rather than to the requirements of this paragraph.				
(2) Except as provided for in 21 CFR §107.50(c)(5), an infant formula manufacturer shall, with respect to each formula covered by this paragraph, comply with the nutrient requirements of section 412(g) of the FD&C Act or of regulations promulgated under section 412(a)(2) of the FD&C Act, and the labeling requirements of subpart B of 21 CFR part 107.				

AUDIT STANDARDS COMPARISON TO THE INFANT FORMULA REGULATIONS

NOTE: This template does not include certain requirements that may be pertinent to determining compliance with 21 CFR Part 106 and 21 CFR Part 107 (including general requirements, definitions, and certain procedural requirements). "Shall" is used to state mandatory requirements. "Should" is used to state recommended or advisory procedures or to identify recommended equipment. In addition to meeting the applicable requirements of 21 CFR Parts 106 and 107, Infant Formula processors of foods intended for consumption in the U.S. are also required to comply with any other pertinent FDA regulatory requirements outside the elements included in the template (e.g., applicable requirements in 21 CFR part 117 related to current good manufacturing practices and preventive controls, 21 CFR Part 113, 114, and 108, as applicable).

PART 107 — INFANT FORMULA	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
(3) Each manufacturer of an infant formula covered by this paragraph shall establish quality control procedures designed to ensure that the infant formula meets applicable nutrient requirements of 21 CFR §107.50, including any special nutritional characteristics for the specific disorders or conditions for which the formula is represented for use. Each manufacturer shall maintain records of such quality control procedures sufficient to permit a public health evaluation of each manufactured batch of infant formula and shall permit any authorized FDA employee at all reasonable times to have access to and to copy and verify the records referred to in this paragraph.				
(4) To retain the exempt status of an infant formula covered by this paragraph, the manufacturer shall submit the information required by 21 CFR §107.50(b)(3) and (4).				
(5) A manufacturer may deviate from the requirements of 21 CFR §107.50(c)(2) only with respect to those specific requirements for which it submits to FDA, at the address specified in 21 CFR §107.50(e)(1), the medical, nutritional, scientific, or technological rationale (including any appropriate animal or human clinical studies). FDA will review that information under 21 CFR §107.50(d).				
(6) The requirements of 21 CFR §107.50 do not apply to an infant formula specially and individually prepared for one or more specific infants on a physician's request.				
(e) Notification requirements. (1) Information required by paragraphs (b) and (c) of this section shall be submitted to the Food and Drug Administration, Center for Food Safety and Applied Nutrition, Office of Nutrition, Labeling, and Dietary Supplements, Infant Formula and Medical Foods Staff (HFS-850), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740.				

NOTE: This template does not include certain requirements that may be pertinent to determining compliance with 21 CFR Part 106 and 21 CFR Part 107 (including general requirements, definitions, and certain procedural requirements). "Shall" is used to state mandatory requirements. "Should" is used to state recommended or advisory procedures or to identify recommended equipment. In addition to meeting the applicable requirements of 21 CFR Parts 106 and 107, Infant Formula processors of foods intended for consumption in the U.S. are also required to comply with any other pertinent FDA regulatory requirements outside the elements included in the template (e.g., applicable requirements in 21 CFR part 117 related to current good manufacturing practices and preventive controls, 21 CFR Part 113, 114, and 108, as applicable).

PART 107 — INFANT FORMULA	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
(2) The manufacturer shall promptly notify the Food and Drug Administration when the manufacturer has knowledge (as defined in section 412(c)(2) of the Federal Food, Drug, and Cosmetic Act) that reasonably supports the conclusion that an exempt infant formula that has been processed by the manufacturer and that has left an establishment subject to the control of the manufacturer may not provide the nutrients required by paragraph (b) or (c) of this section, or when there is an exempt infant formula that may be otherwise adulterated or misbranded and if so adulterated or misbranded presents a risk of human health. This notification shall be made, by telephone, to the Director of the appropriate Food and Drug Administration district office specified in part 5, subpart M of this chapter. After normal business hours (8 a.m. to 4:30 p.m.), contact the Food and Drug Administration Emergency Call Center at 866-300-4374. The manufacturer shall send a followup written confirmation to the Center for Food Safety and Applied Nutrition (HFS-605), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, and to the appropriate FDA district office specified in part 5, subpart M of this chapter.				
Subpart D—Nutrient Requirements				

AUDIT STANDARDS COMPARISON TO THE INFANT FORMULA REGULATIONS

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(a) An infant formula shall contain the following nutrients at a level not less than the minimum level specified and not more than the maximum level specified for each 100 kilocalories of the infant formula in the form prepared for consumption as directed on the container:

Nutrients	Unit of measurement	Minimum level	Maximum level
Protein	Grams	1.8	4.5
Fat	Do.	3.3	6.0
	Percent calories	30	54
Linoleic acid	Milligrams	300	
	Percent calories	2.7	
Vitamins			
Vitamin A	International Units	250	750
Vitamin D	Do.	40	100
Vitamin E	Do.	0.7	
Vitamin K	Micrograms	4	
Thiamine (Vitamin B_1)	Do.	40	
Riboflavin (Vitamin B_2)	Do.	60	
Vitamin B_6	Do.	35	

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Vitamin B_{12}	Do.	0.15					
Niacin[1]	Do.	250					
Folic acid (Folacin)	Do.	4					
Pantothenic acid	Do.	300					
Biotin[2]	Do.	1.5					
Vitamin C (Ascorbic acid)	Milligrams	8					
Choline[2]	Do.	7					
Inositol[2]	Do.	4					
Minerals							
Calcium	Do.	60					
Phosphorus	Do.	30					
Magnesium	Do.	6					
Iron	Do.	0.15	3.0				
Zinc	Do.	0.5					
Manganese	Micrograms	5					
Copper	Do.	60					
Iodine	Do.	5	75				
Selenium	Do.	2	7				

NOTE: This template does not include certain requirements that may be pertinent to determining compliance with 21 CFR Part 106 and 21 CFR Part 107 (including general requirements, definitions, and certain procedural requirements). "Shall" is used to state mandatory requirements. "Should" is used to state recommended or advisory procedures or to identify recommended equipment. In addition to meeting the applicable requirements of 21 CFR Parts 106 and 107, Infant Formula processors of foods intended for consumption in the U.S. are also required to comply with any other pertinent FDA regulatory requirements outside the elements included in the template (e.g., applicable requirements in 21 CFR part 117 related to current good manufacturing practices and preventive controls, 21 CFR Part 113, 114, and 108, as applicable).

PART 107 — INFANT FORMULA	**Audit Standard Language**	**Analysis of Alignment of Audit Standard**	**Description of Gaps and Actions to Align**	**Additional Comments**
<table><tr><td>Sodium</td><td>Milligrams</td><td>20</td><td>60</td></tr><tr><td>Potassium</td><td>Do.</td><td>80</td><td>200</td></tr><tr><td>Chloride</td><td>Do.</td><td>55</td><td>150</td></tr></table> [1]The generic term "niacin" includes niacin (nicotinic acid) and niacinamide (nicotinamide). [2]Required only for non-milk-based infant formulas.				
(b) Vitamin E shall be present at a level of at least 0.7 International Unit of vitamin E per gram of linoleic acid.				
(c) Any vitamin K added shall be in the form of phylloquinone.				
(d) Vitamin B_6 shall be present at a level of at least 15 micrograms of vitamin B_6 for each gram of protein in excess of 1.8 grams of protein per 100 kilocalories of infant formula in the form prepared for consumption as directed on the container.				
(e) The ratio of calcium to phosphorus in infant formula in the form prepared for consumption as directed on the container shall be no less than 1.1 and not more than 2.0.				

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PART 107 — INFANT FORMULA	**Audit Standard Language**	**Analysis of Alignment of Audit Standard**	**Description of Gaps and Actions to Align**	**Additional Comments**
(f) Protein shall be present in an amount not to exceed 4.5 grams per 100 kilocalories regardless of quality, and not less than 1.8 grams per 100 kilocalories of infant formula in the form prepared for consumption as directed on the container when its biological quality is equivalent to or better than that of casein. If the biological quality of the protein is less than that of casein, the minimum amount of protein shall be increased proportionately to compensate for its lower biological quality. For example, an infant formula containing protein with a biological quality of 75 percent of casein shall contain at least 2.4 grams of protein (1.8/0.75). No protein with a biological quality less than 70 percent of casein shall be used.				
Subpart E—Infant Formula Recalls				
§107.210 Firm-initiated product removals.				
(a) If a manufacturer has determined to recall voluntarily from the market an infant formula that is not subject to §107.200 but that otherwise violates the laws and regulations administered by the Food and Drug Administration (FDA) and that would be subject to legal action, the manufacturer, upon prompt notification to FDA, shall administer such voluntary recall consistent with the requirements of this subpart.				
(b) If a manufacturer has determined to withdraw voluntarily from the market an infant formula that is adulterated or misbranded in only a minor way and that would not be subject to legal action, such removal from the market is deemed to be a market withdrawal, as defined in 21 CFR §7.3(j). As required by 21 CFR §107.240(a), the manufacturer shall promptly notify FDA of such violative formula and may, but is not required to, conduct such market withdrawal consistent with the requirements of this subpart pertaining to product recalls.				

AUDIT STANDARDS COMPARISON TO THE INFANT FORMULA REGULATIONS

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PART 107 — INFANT FORMULA	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
§107.230 Elements of an infant formula recall.				
A recalling firm shall conduct an infant formula recall with the following elements:				
(a) The recalling firm shall evaluate in writing the hazard to human health associated with the use of the infant formula. This health hazard evaluation shall include consideration of any disease, injury, or other adverse physiological effect that has been or that could be caused by the infant formula and of the seriousness, likelihood, and consequences of the diseases, injury, or other adverse physiological effect. The Food and Drug Administration will conduct its own health hazard evaluation and promptly notify the recalling firm of the results of that evaluation if the criteria for recall under §107.200 have been met.				
(b) The recalling firm shall devise a written recall strategy suited to the individual circumstances of the particular recall. The recall strategy shall take into account the health hazard evaluation and specify the following: The extent of the recall; if necessary, the public warning to be given about any hazard presented by the infant formula; the disposition of the recalled infant formula; and the effectiveness checks that will be made to determine that the recall is carried out.				

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PART 107 — INFANT FORMULA	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
(c) The recalling firm shall promptly notify each of its affected direct accounts about the recall. The format of a recall communication shall be distinctive, and the content and extent of a recall communication shall be commensurate with the hazard of the infant formula being recalled and the strategy developed for the recall. The recall communication shall instruct consignees to report back quickly to the recalling firm about whether they are in possession of the recalled infant formula and shall include a means of doing so. The recalled communication shall also advise consignees how to return the recall infant formula to the manufacturer or otherwise dispose of it. The recalling firm shall send a followup recall communication to any consignee that does not respond to the initial recall communication.				
(d) If the infant formula presents a risk to human health, the recalling firm shall request that each establishment, at which such infant formula is sold or available for sale, post at the point of purchase of such formula a notice of such recall at such establishment. The notice shall be provided by the recalling firm after approval of the notice by the Food and Drug Administration. The recalling firm shall also request that each retail establishment maintain such notice on display until such time as the Food and Drug Administration notifies the recalling firm that the agency considers the recall completed.				

AUDIT STANDARDS COMPARISON TO THE INFANT FORMULA REGULATIONS

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PART 107 — INFANT FORMULA	**Audit Standard Language**	**Analysis of Alignment of Audit Standard**	**Description of Gaps and Actions to Align**	**Additional Comments**
(e) The recalling firm shall furnish promptly to the appropriate Food and Drug Administration district office listed in 21 CFR part 5, subpart M, as they are available, copies of the health hazard evaluation, the recall strategy, and all recall communications (including, for a recall under 21 CFR §107.200, the notice to be displayed at retail establishments) directed to consignees, distributors, retailers, and members of the public.				
§107.240 Notification requirements.				
(a) *Telephone report.* When a determination is made that an infant formula is to be recalled, the recalling firm shall telephone within 24 hours the appropriate Food and Drug Administration district office listed in 21 CFR §5.115 and shall provide relevant information about the infant formula that is to be recalled.				
(b) *Initial written report.* Within 14 days after the recall has begun, the recalling firm shall provide a written report to the appropriate FDA district office. The report shall contain relevant information, including the following cumulative information concerning the infant formula that is being recalled:				
(1) Number of consignees notified of the recall and date and method of notification, including recalls required by §107.200, information about the notice provided for retail display, and the request for its display.				
(2) Number of consignees responding to the recall communication and quantity of recalled infant formula on hand at each consignee at the time the communication was received.				
(3) Quantity of recalled infant formula returned or corrected by each consignee contacted and the quantity of recalled infant formula accounted for.				
(4) Number and results of effectiveness checks that were made.				

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PART 107 — INFANT FORMULA	**Audit Standard Language**	**Analysis of Alignment of Audit Standard**	**Description of Gaps and Actions to Align**	**Additional Comments**
(5) Estimated timeframes for completion of the recall.				
(c) *Status reports.* The recalling firm shall submit to the appropriate FDA district office a written status report on the recall at least every 14 days until the recall is terminated. The status report shall describe the steps taken by the recalling firm to carry out the recall since the last report and the results of these steps.				
§107.250 Termination of an infant formula recall.				
The recalling firm may submit a recommendation for termination of the recall to the appropriate FDA district office for transmittal to the Recall Coordinator, Division of Enforcement (HFS-605), Office of Compliance, Center for Food Safety and Applied Nutrition, 5001 Campus Dr., College Park, MD 20740, or by email to *CFSAN.RECALL@fda.hhs.gov*, for action. Any such recommendation shall contain information supporting a conclusion that the recall strategy has been effective. The Agency will respond within 15 days of receipt by the Division of Enforcement of the request for termination. The recalling firm shall continue to implement the recall strategy until it receives final written notification from the Agency that the recall has been terminated. The Agency will send such notification, unless the Agency has information from FDA's own audits or from other sources demonstrating that the recall has not been effective. The Agency may conclude that a recall has not been effective if:				
(a) The recalling firm's distributors have failed to retrieve the recalled infant formula; or				
(b) Stocks of the recalled infant formula remain in distribution channels that are not in direct control of the recalling firm.				
§107.280 Records retention.				

AUDIT STANDARDS COMPARISON TO THE INFANT FORMULA REGULATIONS

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PART 107 — INFANT FORMULA	**Audit Standard Language**	**Analysis of Alignment of Audit Standard**	**Description of Gaps and Actions to Align**	**Additional Comments**
Each manufacturer of an infant formula shall make and retain such records respecting the distribution of the infant formula through any establishment owned or operated by such manufacturer as may be necessary to effect and monitor recalls of the formula. Such records shall be retained for at least 1 year after the expiration of the shelf life of the infant formula.				

Appendix **FDA Reviewed Submission Content for §106.120 and §106.121**	**Additional Comments**
§106.120 New infant formula submission.	
(b) The new infant formula submission shall include:	
(1) The name and description of the physical form (e.g., powder, ready-to feed, or concentrate) of the infant formula;	
(2) An explanation of why the formula is a new infant formula;	
(3) The quantitative formulation of each form of the infant formula that is the subject of the notice 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, and, when applicable, a description of any reformulation of the infant formula, including a listing of each new or changed ingredient and a discussion of the effect of such changes on the nutrient levels in the formulation;	
(4) A description, when applicable, of any change in processing of the infant formula. Such description shall identify 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;	

AUDIT STANDARDS COMPARISON TO THE INFANT FORMULA REGULATIONS

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Appendix **FDA Reviewed Submission Content for §106.120 and §106.121**	**Additional Comments**
(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 §106.96, shall be provided by a submission that complies with §106.121;	
(ii) Assurance that the formula complies with the nutrient content requirements, which are set forth in 21 CFR §107.100, shall be provided by a statement that the formula will not be marketed unless it meets the nutrient requirements of 21 CFR §107.100, as demonstrated by testing required under subpart C of 21 CFR part 106; and	
(6) Assurance that the processing of the infant formula complies with section 412(b)(2) of the FD&C Act. Such assurance shall include:	
(i) A statement that the formula will be produced in accordance with subparts B and C of 21 CFR part 106; and	
(ii) The basis on which each ingredient meets the requirements of §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.	
(7) If the manufacturer is requesting an exemption under §106.91(b)(1)(ii), the manufacturer shall include 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.	
(c) For a new infant formula for export only, a manufacturer may submit, in lieu of the information required under 21 CFR §106.120(b)(5) and 21 CFR §106.120(b)(6), a statement certifying that the infant formula meets the specifications of the foreign purchaser, the infant formula does not conflict with the laws of the country to which it is intended for export, the infant formula is labeled on the outside of the shipping package to indicate that it is intended for export only, and the infant formula will not be sold or offered for sale in domestic commerce. Such manufacturer shall also submit a statement certifying that it has adequate controls in place to ensure that such formula is actually exported.	

AUDIT STANDARDS COMPARISON TO THE INFANT FORMULA REGULATIONS

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Appendix **FDA Reviewed Submission Content for §106.120 and §106.121**	**Additional Comments**
(d) The submission will not constitute notice under section 412 of the Federal Food, Drug, and Cosmetic Act unless it complies fully with 21 CFR §106.120(b), as applicable, and the information that it contains is set forth in a manner that is readily understandable. The Agency will notify the manufacturer if the notice is not complete because it does not meet the requirements in section 412(c) and (d) of the Federal Food, Drug, and Cosmetic Act.	
(e) If a new infant formula submission contains all the information required by 21 CFR §106.120(b), as applicable, the Food and Drug Administration will acknowledge its receipt and notify the manufacturer of the date of receipt. The date that the Agency receives a new infant formula submission that is complete is the filing date for such submission. The manufacturer shall not market the new infant formula before the date that is 90 days after the filing date. If the information in the submission does not provide the assurances required under section 412(d)(1) of the Federal Food, Drug, and Cosmetic Act and the regulations 21 CFR Chapter 1, the Food and Drug Administration will so notify the manufacturer before the expiration of the 90th day.	
(f) If the manufacturer provides additional information in support of a new infant formula submission, the Agency will determine whether the additional information is a substantive amendment to the new infant formula submission. If the Agency determines that the new submission is a substantive amendment, the Food and Drug Administration will assign the new infant formula submission a new filing date. The Food and Drug Administration will acknowledge receipt of the additional information and, when applicable, notify the manufacturer of the new filing date, which is the date of receipt by the Food and Drug Administration of the information that constitutes the substantive amendment to the new infant formula submission.	
(g) Submissions relating to exempt infant formulas are subject to the provisions of §107.50 of 21 CFR part 107.	
§106.121 Quality factor assurances for infant formulas.	
To provide assurance that an infant formula meets the requirements for quality factors set forth in §106.96, the manufacturer shall submit the following data and information:	
(a) Unless the manufacturer of a new infant formula can claim an exemption under §106.96(c)(1) or (c)(2), the following assurances shall be provided to ensure that the requirements of §106.96(a) and (b) have been met:	
(1) An explanation, in narrative form, setting forth how requirements for quality factors in §106.96(b) have been met;	

AUDIT STANDARDS COMPARISON TO THE INFANT FORMULA REGULATIONS

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Appendix **FDA Reviewed Submission Content for §106.120 and §106.121**	**Additional Comments**
(2) Records that contain the information required by §106.96(b) to be collected during the study for each infant enrolled in the study. The records shall be identified by subject number, age, feeding group, gender, and study day of collection.	
(3) Data, which shall include:	
(i) Statistical evaluation for all measurements, including group means, group standard deviations, and measures of statistical significance for all measurements for each feeding group at the beginning of the study and at every point where measurements were made throughout the study, and	
(ii) Calculations of the statistical power of the study before study initiation and at study completion.	
(4) A report on attrition and on all occurrences of adverse events during the study, which shall include:	
(i) Identification of the infant by subject number and feeding group and a complete description of the adverse event, including comparisons of the frequency and nature of occurrence in each feeding group and information on the health of the infant during the course of the study, including the occurrence and duration of any illness;	
(ii) A clinical assessment by a health care provider of the infant's health during each suspected adverse event; and	
(iii) A list of all subjects who did not complete the study, including the subject number and the reason that each subject did not complete the study.	
(b) If the manufacturer is requesting an exemption from the growth monitoring study requirements under §106.96(c)(1), 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 §106.96(c)(1).	
(c) If the manufacturer is requesting an exemption under §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.	
(d) If the manufacturer is requesting an exemption under §106.96(c)(2)(ii), the manufacturer shall include a detailed description of the change and an explanation of why the change made by the manufacturer to an existing infant formula does not the affect the ability of the formula to support normal physical growth.	

AUDIT STANDARDS COMPARISON TO THE INFANT FORMULA REGULATIONS

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Appendix **FDA Reviewed Submission Content for §106.120 and §106.121**	**Additional Comments**
(e) If the manufacturer is requesting an exemption under §106.96(c)(2)(iii), the manufacturer shall include a detailed description of the two formulations and an explanation of why the quality factor requirement of normal physical growth is 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.	
(f) Unless the manufacturer of a new infant formula is requesting an exemption under §106.96(g), the results of the Protein Efficiency Ratio bioassay shall be provided in accordance with §106.96(f).	
(g) If the manufacturer is requesting an exemption under §106.96(g)(1), 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 §106.96(g)(1).	
(h) If the manufacturer is requesting an exemption under §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.	
(i) If the manufacturer is requesting an exemption under §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.	
(j) A statement certifying 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 that the manufacturer is not aware of any information or data that would show that the formula does not meet the requirements for quality factors.	