requirements of § 106.70(a) before it is released.

(c) An individual qualified by training or experience shall conduct an investigation of a finding that a batch of infant formula fails to meet any manufacturer's specifications.

§ 106.80 Traceability.

(a) Manufacturers shall ensure traceability by coding infant formulas in conformity with the coding requirements prescribed in § 113.60(c) of this chapter for thermally processed low-acid foods packaged in hermetically-sealed containers, except as provided in paragraph (b) of this section.

(b) Batches of powdered infant formula that are manufactured in stages over more than 1 day, in lieu of being coded in accordance with § 113.60(c) of this chapter, may 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 batch, 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.

Manufacturers of an infant formula, or an agent of such manufacturers, shall conduct regularly scheduled audits to determine whether the manufacturer has complied with the current good manufacturing practice regulations in this subpart. These audits shall be performed by an individual who, as a result of education, training, and experience, is knowledgeable in all aspects of infant formula production and of the agency's regulations concerning current good manufacturing practice but who has no direct responsibility for the matters being audited.

Subpart C—Quality Control Procedures

§ 106.91 General quality control.

(a) *Nutrient testing to ensure that each batch of infant formula provides nutrients in accordance with § 107.100.* Manufacturers shall test each batch as follows:

(1) Each nutrient premix used in the manufacture of an infant formula shall be tested for each nutrient 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 batch 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 batch of infant formula.

(3) At the final-product-stage, before distribution of an infant formula, each batch shall be tested for vitamins A, C, E, and thiamin.

(4) During the manufacturing process or at the final-product-stage, before distribution, each batch shall be tested for all nutrients required to be included in such formula under § 107.100 of this chapter and for any nutrient added by the manufacturer for which testing is not conducted for compliance with paragraphs (a)(1) or (a)(3) of this section.

(b) *Stability testing.* Every 3 months, manufacturers shall collect representative samples from the final-product-stage of one batch of each physical form (powder, ready-to-feed, or concentrate) of each infant formula, at each manufacturing facility. The manufacturer shall test these samples for each nutrient required under § 107.100 of this chapter and for any nutrient added by the manufacturer. The frequency of such testing shall be at the beginning, midpoint, and end of the shelf life of the infant formula and, depending on the nutrient and its stability within the matrix of the formulation, with additional frequency as is necessary to ensure that such formula complies with section 412 of the Federal Food, Drug, and Cosmetic Act (the act) throughout the shelf life of the infant formula; except that:

(1) If the infant formula is a new infant formula, manufacturers shall collect a representative sample from the final-product-stage of each physical form (powder, ready-to-feed, or concentrate) of the first batch of the new infant formula and test these samples according to the requirements of this section; and

(2) If an infant formula has been changed in formulation or in processing in a way that does not make it a new infant formula but that may affect whether it is adulterated under section 412(a) of the act, the manufacturer shall collect a representative sample from the final-product-stage of each physical form (powder, ready-to-feed, or concentrate) of the first batch of the infant formula and shall test these samples according to the frequency required by this section for each nutrient that has been or may have been affected by the change.

(c) *Quality control records.* Manufacturers shall make and retain quality control records in accordance with § 106.100(e)(5)(i) and (f)(7).

§ 106.92 Audits of quality control procedures.

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 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 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. These audits shall be performed by an individual who, as a result of education, training, and experience, is knowledgeable in all aspects of infant formula production and of the agency's regulations concerning quality control procedures but who has no direct responsibility for the matters being audited.

Subpart D—Conduct of Audits

§ 106.94 Audit plans and procedures.

(a) Manufacturers shall develop and follow a written audit plan that is available at the manufacturing facility for FDA 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 assure that an infant formula provides nutrients in accordance with section 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, but not be limited to:

(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 standard or 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 Quality factors in infant formulas.

(a) All infant formulas shall, when fed to infants as a sole source of nutrition, be of sufficient quality to meet the nutritional requirements for healthy growth. The regulations set forth in this subpart define the minimum quality factors for infant formulas.

(b) All infant formulas shall be capable of supporting normal physical growth of infants.

(c) All infant formulas shall be formulated and manufactured such that the protein is of sufficient biological quality to meet the protein requirements of infants.

§ 106.97 Assurances for quality factors.

(a) *General quality factor of normal physical growth.* (1) The manufacturer shall conduct an adequate and well-controlled clinical study, 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.

(i) The manufacturer shall:

(A) Conduct a clinical study that is no less than 4 months in duration, enrolling infants no more than 1 month old at time of entry into the study.

(B) Collect and maintain data in the study on anthropometric measures of physical growth, including body weight, recumbent length, head circumference, and average daily weight increment, and plot the data on National Center for Health Statistics (NCHS) reference percentile body weight and body length curves. The NCHS growth charts are incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the Office of Constituent Operations (HFS–565), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204, may be examined at the Office of Special Nutritionals (HFS–456), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

(C) Collect anthropometric measurements at the beginning of the clinical study, at 2 weeks, at 4 weeks, at least monthly thereafter, and at the conclusion of the study.

(ii) The clinical study protocol should:

(A) Describe the scientific basis and objectives of the study, the planned control and treatment feeding regimens, the entrance criteria used to enroll infants in the study, the method of randomization used for the assignment of infants to feeding groups, the collection of specific measurements and other data, the methods used to limit sources of bias, and the planned methods of statistical analysis;

(B) Describe the necessary qualifications and experience of investigators;

(C) Be reviewed and approved by an Institutional Review Board (IRB) in accordance with part 56 of this chapter. The manufacturer shall establish procedures to obtain written informed consent from parents or legal representatives of the infants enrolled in the study in accordance with part 50 of this chapter;

(D) Explain how the study population represents the population for which the new infant formula is intended and how the study addresses the intended conditions of use of the formula.

(E) Describe the sample size calculations and the power calculations and the basis for selecting the sample size and study design;

(F) Describe the plan to identify and evaluate any adverse effects;

(G) Describe the quality control procedures used to ensure the validity and reliability of the measurements collected.

(H) Describe and compare the composition of the test and control formulas.

(I) Describe the basis upon which the test formula is appropriate for use in evaluating the formula that the manufacturer intends to market, if the test formula used in a study is not identical to the formula that is intended to be marketed in the United States.

(2) The manufacturer may request an exemption from the requirements of paragraph (a)(1) of this section if:

(i) The manufacturer has similar experience using an ingredient, an ingredient mixture, or a processing method in the production of an infant formula marketed in the United States and can demonstrate that infant formula made with that ingredient, ingredient mixture, or processing method meets the quality factor requirements in § 106.96;

(ii) The manufacturer markets a formulation in more than one form (e.g., liquid and powdered forms) and can demonstrate that 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;

(iii) The manufacturer can demonstrate that the requirements of paragraph (a)(1) of this section are not appropriate for evaluation of a specific infant formula, and that an alternative method or study design for showing that the formula supports healthy growth in infants fed it as their sole source of nutrition is available.

(b) *Specific quality factor for protein quality of infant formula.* (1) The manufacturer shall collect and maintain data that establish that the biological quality of protein in an infant formula is sufficient to meet the protein requirements of infants. The manufacturer shall establish the biological quality of the protein in its infant formula by demonstrating that the protein source supports adequate growth using the Protein Efficiency Ratio (PER) rat bioassay described in the "Official Methods of Analysis of the Association of Official Analytical Chemists," 16th ed., sections 43.3.04 and 43.3.05, "AOAC Official Method 960.48 Protein Efficiency Ratio Rat Bioassay" which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the Association of Official Analytical Chemists, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20857, or the Office of Special Nutritionals (HFS–456), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or may be examined at the Office of the Federal Register, 800 North Capitol St. NW., Washington, DC. If the manufacturer is unable to conduct a PER rat bioassay because of the composition of the protein in the formula, then it shall demonstrate that the amino acid composition of the protein meets the known amino acid requirements of infants for whom the formula is intended.

(2) The manufacturer may request an exemption from the requirements of paragraph (b)(1) of this section if:

(i) The protein source, including any processing method used to produce the protein source, is already used in another infant formula marketed in the United States, manufactured by the same manufacturer, and the manufacturer can demonstrate that such infant formula meets the quality factor requirements prescribed in § 106.96;

(ii) The protein source, including any processing methods used to produce the protein source, is not a major change from the infant formula it replaces, and the manufacturer can demonstrate that the infant formula it replaces meets the

quality factor requirements prescribed in § 106.96.

6. In newly redesignated subpart F, § 106.100 is amended by revising paragraphs (e), (f), (g), (j), and (k)(3), and by removing and reserving paragraph (h) to read as follows:

§ 106.100 Records.

* * * * *

(e) *Batch production and control records.* For each batch of infant formula, manufacturers shall prepare and maintain records that include complete information relating to the production and control of the batch. These records shall include but are not limited to:

(1) The master manufacturing order. The master manufacturing order shall include but is not limited to:

(i) The significant steps in the production of the batch and the date on which each significant step occurred;

(ii) The identity of equipment and processing lines used in producing the batch, if the plant in which the formula is made includes more than one set of equipment or more than one processing line;

(iii) The identity of each batch or lot of ingredients, containers, and closures used in producing the batch of formula;

(iv) The amount of each ingredient to be added to the batch of infant formula and a check (verification) that the correct amount was added; and

(v) Copies of all labeling used and the results of examinations conducted during the finishing operations to provide assurance that containers and packages in the lot 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 their production process where control is deemed necessary to prevent adulteration. These records shall include, but not be limited to:

(i) A list of the standards or specifications established at each point, step, or stage in their production process where control is deemed necessary to prevent adulteration including documentation of the scientific basis for each standard or specification;

(ii) The actual values obtained during the monitoring operation, any deviations from established standards or specifications, and any corrective actions taken;

(iii) Identification of the person monitoring each point, step, or stage in their production process where control is deemed necessary to prevent adulteration.

(4) The conclusions and followup, along with the identity, of the individual qualified by training or experience who investigated:

(i) Any deviation from the master manufacturing order and any corrective actions taken;

(ii) A finding that a batch or any of its ingredients failed to meet the infant formula manufacturer's specifications; and

(iii) A failure to meet any specification or standard 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 batch of infant formula, including testing on the in-process batch, at the final-product stage, and on finished product throughout the shelf life of the product. The results recorded shall include but are not limited to:

(i) The results of all quality control testing conducted, in accordance with § 106.91(a) and (b), to verify that each nutrient required by § 107.100 of this chapter is present in each batch of infant formula at the level required by § 107.100, and that any nutrient added by the manufacturer is present at the appropriate level with:

(A) A summary table identifying the stages of the manufacturing process at which the nutrient analysis for each required nutrient under § 106.91(a) is conducted, and

(B) A summary table on the stability testing program, including the nutrients tested and the frequency of testing of nutrients throughout the shelf life of the product under § 106.91(b); and

(ii) For powdered infant formula, the results of any testing conducted in accordance with § 106.55(b) to verify compliance with the microbiological quality standards in § 106.55(c).

(f) Manufacturers shall make and retain all records pertaining to current good manufacturing practice as described in subpart B of this part, including but not limited to:

(1) Records, in accordance with § 106.20(f)(3), of the frequency and results of testing of the water used in the production of infant formula;

(2) Records, in accordance with § 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 (testing for accuracy against a known reference standard) shows that a specification or standard 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 § 106.30(e)(3)(ii), of the temperatures monitored for cold storage compartments and thermal processing equipment.

(4) Records, in accordance with § 106.30(f), on equipment cleaning, sanitizing, and maintenance that show the date and time of such cleaning, sanitizing, and maintenance and the lot number of each batch of 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 § 106.35(c), on all automatic (mechanical or electronic) equipment used in the production or quality control of infant formula. These records shall include but not be limited to:

(i) A list of all systems used with a description of computer files and the 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 diskettes, 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 § 106.40(g), on ingredients, containers, and closures used in the manufacture of infant formula. These records shall include, but are not limited to:

(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, and closure, if different from the supplier;

(v) The date of receipt;

(vi) The receiving code as specified; and

(vii) The results of any test or examination (including retesting and reexamination) performed on the ingredients, containers, and closures and the conclusions derived therefrom 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 § 106.55(c) and the methodology used to do quality control testing, in accordance with § 106.91(a) and (b).

(g) The manufacturer shall maintain all records pertaining to distribution of the infant formula, including records that show that products produced for export only are exported. Such records shall include, but not be limited to, all information and data necessary to effect and monitor recalls of the manufacturer's infant formula products in accordance with subpart E of part 107 of this chapter.

(h) [Reserved]

* * * * *

(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 § 106.100(n), but need not be made available to FDA.

(k) * * *

(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.

* * * * *

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, the manufacturer of such formula shall register with the Food and Drug Administration, Center for Food Safety and Applied Nutrition, Office of Special Nutritionals, Division of Programs and Policy Enforcement (HFS–455), Infant Formula Coordinator, 200 C St. SW., Washington, DC 20204. An original and two copies of this registration shall be submitted.

(b) The new infant formula registration shall include:

(1) The name of the new infant formula,

(2) The name of the manufacturer,

(3) The place of business of the manufacturer, and

(4) All establishments at which the manufacturer intends to manufacture such new infant formula.

§ 106.120 New infant formula submission.

(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 copies of the notice of its intent to do so shall be submitted.

(b) The new infant formula submission shall include:

(1) The name and 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 (for liquid formulas) or units per dry weight (for powdered formulas). When applicable, the submission shall include 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 (including processing times and temperatures);

(5) Assurance that the infant formula will not be marketed unless the formula meets the quality factor requirements of section 412(b)(1) of the Federal Food, Drug, and Cosmetic Act (the act) and the nutrient content requirements of section 412(i) of the act.

(i) Assurance that the formula meets the quality factor requirements, which are set forth in subpart E of this part, 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 § 107.100 of this chapter, shall be provided by a statement assuring that the formula will not be marketed unless it meets the nutrient requirements of § 107.100 of this chapter, as demonstrated by testing required under subpart C of this part;

(6) Assurance that the processing of the infant formula complies with section 412(b)(2) of the act. Such assurance shall include but not be limited to:

(i) A statement that the formula will be produced in accordance with subparts B and C of this part;

(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 issued by the agency, or that it is 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.

(c) For products for export only, a manufacturer may submit, in lieu of the information required under paragraph (b) of this section, a statement that the infant formula meets the specifications of the foreign purchaser, does not conflict with the laws of the country to which it is intended for export, is labeled on the outside of the shipping package to indicate that it is intended for export only, and will not be sold or offered for sale in domestic commerce.

(d) The submission will not constitute notice under section 412 of the act unless it complies fully with paragraph (b) of this section, and the information that it contains is set forth in a manner that is readily understandable. The agency will notify the submitter if the notice is not adequate because it does not meet the requirements of section 412(c) and (d) of the act.

(e) If a new infant formula submission is adequate, FDA will acknowledge its receipt and notify the manufacturer of the date of receipt. The date that the agency receives the new infant formula

submission is the filing date for the submission. The manufacturer shall not market the new infant formula before the date that is 90 days after the filing date.

(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, FDA will assign the new infant formula submission a new filing date. FDA 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 FDA of the information that constitutes the substantive amendment to the new infant formula submission.

§ 106.121 Quality factor submission.

To provide assurance that an infant formula meets the quality factor requirements set forth in subpart E of this part, the manufacturer shall submit the following data and information:

(a) An explanation, in narrative form, setting forth how all quality factor requirements of subpart E of this part have been met.

(b) Records that contain the information required by proposed § 106.97 (a)(1)(i) and (a)(1)(ii) 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.

(c)(1) 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.

(2) Calculation of the statistical power of the study at its completion.

(d) A report on attrition and on all occurrences of adverse events during the study, which shall include:

(1) 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;

(2) A clinical assessment, by a health care provider, of the infant's health during each suspected adverse event;

(3) A complete listing of all infants who did not complete the study, including the infant's subject number and the reason that each infant left the study.

(e) The results of the Protein Efficiency Ratio, in accordance with § 106.97(b).

(f) A statement certifying that the manufacturer has collected and considered all information and data concerning the ability of the infant formula to meet the quality factor requirements, and that the manufacturer is not aware of any information or data that would show that the formula does not meet the quality factors requirements.

§ 106.130 Verification submission.

(a) Manufacturers shall, after the first production and before the introduction into interstate commerce of the new infant formula, verify in a written submission to FDA at the address given in § 106.110(a), that the infant formula complies with the requirements of the Federal Food, Drug, and Cosmetic Act (the act) and is not adulterated. An original and two copies of this verification shall be submitted.

(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;

(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 § 107.100 of this chapter 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, including testing required by current good manufacturing practice, designed to prevent adulteration of this formula in accordance with subparts B and C of this part.

(c) The submission will not constitute written verification under section 412(d)(2) of the act when any data prescribed in paragraph (b) of this section are lacking or are not set forth so as to be readily understood. In such circumstances the agency will notify the submitter that the notice is not adequate.

§ 106.140 Submission concerning a change in infant formula that may adulterate the product.

(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 (the act), it 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.

(b) The submission shall include:

(1) The name and physical form of the infant formula (i.e., powder, ready-to-feed, or concentrate);

(2) An explanation of why the change in formulation or processing may affect whether the formula is adulterated; and

(3) A submission that 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 is the subject of this submission, together with the identification number assigned by the agency to the relevant infant formula submission, may be provided in lieu of such submission.

(c) The submission will not constitute notice under section 412 of the act unless it complies fully with paragraph (b) of this section, and the information that it contains is set forth in a manner that is readily understandable. The agency will notify the submitter if the notice is not adequate because it does not meet the requirements of section 412(d)(3) of the act.

§ 106.150 Notification of an adulterated or misbranded infant formula.

(a) A manufacturer shall promptly notify FDA in accordance with paragraph (b) of this section, when the manufacturer has knowledge (that is, the 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 act or by regulations issued under section 412(i)(2); or