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 §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 §107.20(c) of this chapter; or

(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 §106.80 for each product, and the ''use by'' date for each product applied to satisfy the requirement of §107.20(c) of this chapter.

§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.

(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.

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 paragraph (a) of this section 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:

(1) Each nutrient premix used in the manufacture of an infant formula shall be tested for each nutrient (required under §107.100 of this chapter 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 §107.100 of this chapter for which testing is not conducted for compliance with paragraphs (a)(1) or (a)(3) of this section and for any nutrient added by the manufacturer for which testing is not conducted for compliance with paragraph (a)(1) of this section.

(b) A manufacturer shall test each production aggregate of finished product for nutrients as follows:

(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 under §107.100 of this chapter 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 this section if the manufacturer of a new infant formula requests an exemption and provides analytical data, as required under §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 paragraph (b)(1)(i) of this section would be required to test the first production aggregate according to the requirements of §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 §107.100 of this chapter and all other nutrients added by the manufacturer. The manufacturer shall repeat such testing at the end of the shelf life of the product.

(3) If the results of the testing required by paragraph (b)(1) of this section 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 paragraph (b)(1) of this section on a subsequently produced production aggregate to substantiate the shelf life of the infant formula or