

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 in-

fant 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