§ 106.25 In-process control.

(a) Except as provided in §106.20(b), no analysis before use in manufacturing is needed for ingredients that are generally stable in shipping and storage, and that either are received under a supplier's guarantee or certification that the mixture has been analyzed as to nutrient composition or are labeled as having nutrient compositions complying with specifications in the U.S. Pharmacopeia, the National Formulary, the Food Chemicals Codex, or other similar recognized standards.

(b) Unless each batch of finished product is analyzed as specified in §106.30(b)(1) before release of product for commercial or charitable distribution, the following shall apply:

(1) When an ingredient is relied upon as a source of a nutrient(s) and when evidence indicates that such nutrient(s) in that ingredient is likely to be affected adversely by shipping or storage conditions, the manufacturer shall analyze that ingredient for each relied-upon nutrient that may be affected, using validated analytical methods.

(2) Ingredients, including nutrient premixes, that are either without a supplier's guarantee or certification, or not labeled as complying with prescribed standards, shall be sampled and analyzed for each relied-upon nutrient by the manufacturer, except that ingredients used as a major source of protein or fat need not be analyzed for each relied-upon nutrient if the manufacturer has records to show that each relied-upon nutrient is present at a reasonably constant level. Nutrient premixes prepared by the infant formula manufacturer shall be sampled and analyzed for each relied-upon nutrient unless the supplier has sampled and analyzed each batch of premix for each relied-upon nutrient and has so certified in writing.

§ 106.25 In-process control.

(a) For each infant formula, a master manufacturing order shall be prepared and approved by a responsible official of the manufacturer. The manufacturer shall establish a quality control system that assures and verifies the addition of each ingredient specified in the manufacturing order.

(b) Unless each batch of finished product is analyzed as specified in §106.30(b)(1), the manufacturer shall analyze each in-process batch for:

(1) Solids;

(2) Protein, fat, and carbohydrates (carbohydrates either by analysis or by mathematical difference);

(3) The indicator nutrient(s) in each nutrient premix;