In the CCFP infant meal pattern, a site must offer at least one iron-fortified infant formula that is regulated by the Food and Drug Administration (FDA). The FDA has strict nutrition and safety standards for infant formula to make sure infants are getting the nutrients they need for healthy growth.

The infant formula must be FDA approved, should not be on the FDA Exempt Infant Formula list, and must be iron-fortified.

All infant formulas sold in the United States are regulated by the FDA. If an infant formula is bought from a place online or in person outside of the United States, it is probably not regulated by the FDA and should not be used.

Previously, USDA-FNS provided a list of Iron-Fortified Infant Formulas That Do Not Require a Medical Statement. FNS no longer maintains such a list due to the continuous development of new or re-formulated infant formula products making an accurate, all-inclusive list impractical.

The following criteria may be used to determine whether a formula is eligible for reimbursement:

1. Ensure that the formula is not an FDA Exempt Infant Formula. An exempt infant formula is an infant formula labeled for use by infants who have inborn errors of metabolism or low birth weight, or who otherwise have unusual medical or dietary problems, as defined in 21 CFR 107.3.

   More information and a list of FDA Exempt Infant Formulas can be found at: http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/InfantFormula/ucm106456.htm.

2. Look for “Infant Formula with Iron” or a similar statement on the front of the formula package. All iron-fortified infant formulas must have this type of statement on the package.

3. Use the nutrition facts label as a guide to ensure that the formula is iron-fortified. The nutritive values of each formula are listed on the product’s nutrition facts label. To be considered iron-fortified, an infant formula must have 1 mg of iron or more per 100 calories of formula when prepared in accordance with label directions.

FDA Exempt Infant Formulas are special infant formulas that are meant only for babies who have an unusual medical or dietary restriction. An exempt infant formula can only be served as part of a reimbursable meal if the substitution is supported by a medical statement signed by the infant’s health care provider.