Creditable Infant Formulas in the CCFP

The <u>CCFP infant meal pattern</u> requires a site to 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. All infant formulas sold in the United States are regulated by the FDA.

Infant formulas manufactured outside the United States are not creditable, but the FDA has provided a pathway for manufacturers of infant formula products that were imported, sold, and/or distributed under a letter of enforcement discretion received based on factors described in a guidance to industry issued on May 16. 2022 to continue marketing their products while they work toward meeting all applicable FDA requirements. The list of these approved foreign infant formulas can be found here: www.fda.gov/food/infantformula-quidance-documents-regulatory-information/enforcement-discretion-manufacturers-increase-infantformula-supplies. The infant formulas on this list are creditable in the CCFP.

Infant formula served in a CCFP reimbursable meal must be FDA approved, should not be on the FDA Exempt Infant Formula list, and must be iron-fortified.

How to determine if an infant formula is eligible for reimbursement:

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

More information and a list of FDA Exempt Infant Formulas can be found at: www.fda.gov/food/infantformula-guidance-documents-regulatory-information/exempt-infant-formulas-marketed-united-statesmanufacturer-and-category

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.



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 1mg of iron or more per 100 calories of formula when prepared in accordance with label directions.

