



North Carolina Department of Health and Human Services
Division of Public Health – Women’s & Children’s Health Section

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CACFP 02-39

MEMORANDUM

TO: Institutions Participating in the Child and Adult Care Food Program

FROM: Arnette Cowan, MS, RD, LDN,
Supervisor, Special Nutrition Programs Unit

SUBJECT: Update on Iron-Fortified Infant Formulas and Medical Statement Requirements

The Child and Adult Care Food Program (CACFP) has announced an updated list of iron-fortified infant formulas that require medical statements in addition to an update of those that do not require medical statements.

The United States Department of Agriculture’s (USDA) Food and Nutrition Service (FNS) recommends that schools, centers or day care homes offer the type of formula suggested by the infant’s health care provider. If the school or child care facility offers a different type of formula, the infant’s parent may choose to decline the formula offered and to provide another formula.

Meals that contain only infant formula supplied by a parent are not reimbursable under the guidelines of the CACFP.

A medical statement is required to serve any infant formulas which do not meet the definition of infant formula in the CACFP. According to CACFP regulations, infant formula is defined as “any iron-fortified formula intended for dietary use as a sole source of food for normal, healthy infants served in liquid state at manufacturer’s recommended dilution.”

Iron-fortified formula as defined by the Food and Drug Administration (FDA) is a product “containing 1 milligram or more of iron in a quantity of product that supplies 100 kilocalories when prepared in accordance with label directions for infant consumption.” The number of milligrams of iron per 100 kilocalories of formula is on the nutritional label of infant formulas. The CACFP definition of infant formula has sufficient flexibility to allow milk and soy-based formula for healthy infants and lactose intolerant infants who do not have other medical conditions which prohibit the use of formula as defined.



Formulas which require a statement from a recognized medical authority are identified as follow:

1. **Low-iron infant formulas.** These infant formulas contain less than 1 milligram of iron per 100 kilocalories of formula. Examples include the low-iron versions of **Enfamil** and **Similac**. The labels on these formulas do not indicate that they are fortified with iron.
2. **“Follow-up”/ “Toddler”** formulas when served to infants less than a specified age. Follow-up *formulas* (i.e, *formulas designed for older infants or toddlers who are consuming solid foods*) are not intended for dietary use as a sole source of food for infants. A medical statement is required to serve the follow-up formulas to any infant less than four months of age. A medical statement is required to serve the follow-up “Toddler” formulas to any infant less than six months of age.
3. **Exempt infant formulas.** These are a group of specialty infant formulas that are intended for use by infants who have an inborn error of metabolism or low birth weight or who otherwise have an unusual medical or dietary problem. Some examples of these formulas include **Nutramigen**, **Pregestimil**, **Alimentum**, and **Lofenalac**. If a child care provider has a question about whether an infant formula falls into this “exempt” category, the provider should contact his or her sponsor or regional consultant for technical assistance.

Through CACFP, reimbursement is allowed for a meal which includes a substituted food item such as infant formula provided by the parent for medical reasons as long as the provider supplies at least one required meal component. A medical statement is required for all infant formulas which do not meet the regulatory definition for infant formula stated above.

Additionally, the FNS has provided a follow-up on iron-fortified infant formulas that do not require a medical statement when they are served to infants at the following ages:

Infants age 4 months and older:

- These types of formulas do not require medical statements when they are served to infants ages 4 months and older. (*A medical statement is required if any of the following formulas are served to infants younger than 4 months of age*)
 - Carnation Follow-Up Formula (*milk-based*) – This formula is specifically designed for infants ages 4 to 12 months and older, who are eating cereal and other baby foods.
 - Carnation Follow-Up Soy Formula (*soy-based*) – This formula is specifically designed for infants ages 4 to 12 months and older who are eating cereal and other baby foods.
 - Gentle Moments 2 Infant Formula with Iron (milk-based, sold through Wal-Mart) – This formula is designed for infants ages 4 months and older who are adjusting to solid foods.
 - Wyeth-produced Private Label Store Brands “Follow-On” Infant Formulas – These types of formulas are designed for infants 4 months and older and are intended to replace traditional starter formula when an infant is eating cereal and other baby foods. They are not intended to replace breast milk. These formulas have been specially formulated for use as a supplement to the solid food portion of the older infant’s diet:
 - Albertson’s Baby Basics 2 Follow-on Infant Formula Powder (*sold through a variety of stores*)
 - Hill Country Fare 2 Follow-on Infant Formula (*sold through H.E. Buttor H-E-B*)
 - Kroger Comforts 2 Follow-on Infant Formula
 - Parent’s Choice 2 Follow-on Infant Formula (*sold through Wal-Mart*)

- Safeway Select 2 Follow-on Infant Formula (*sold through a variety of stores*)
- Target Healthy Baby Formula for Older Infants
- Wegman's 2 Follow-on Infant Formula

Infants ages 6 months and older:

The following types of formula do not require a medical statement when they are served to infants 6 months of age and older. (*A medical statement is required if any of them are served to infants younger than 6 months of age*):

- Enfamil Next Step Toddler Formula (*milk-based*) – This formula is designed as an alternative to cow's milk for the older infant or toddler (*6 months old and older, per the manufacturer*). It is not being marketed as an alternative to "Enfamil with Iron" or other iron-fortified infant formulas which are designed for infants from birth to 12 months of age.
- Enfamil Next Step Soy Toddler Formula (*soy-based*) – This formula is designed as an alternative to cow's milk for the toddler with milk sensitivities.
- Ross Similac 2 Toddler Formula (*milk-based*) - This formula is an alternative to cow's milk for the older infants or toddler. (*6 months old and older, according to the manufacturer*). It is not marketed as an alternative to "Similac with Iron" or any other iron-fortified infant formulas that are designed for infants birth to 12 months of age.
- Ross Isomil 2 Soy Toddler Formula (*soy-based*) – This formula is designed as an alternative to cow's milk for the toddler with mild sensitivities.

Included with the memorandum are lists outlining infant formulas that do not require a medical statement.

AC/ERB

cc: SNP Staff
Auditors