

September 14, 2004

SUBJECT: Clarification on Acceptable Infant Formulas

TO: John Magnarelli, Director
Special Nutrition Programs
Northeast Regional Office

This memorandum is in response to questions raised by the Connecticut State agency:

1. Must a formula served (in the CACFP) be listed exactly as it says on the Child and Adult Care Food Program Approved List?

The answer is a qualified no. The current list of the *Iron-Fortified Infant Formulas That Do Not Require a Medical Statement* is NOT an inclusive list, because new infant formula products are continually being developed.

According to the Child and Adult Care Food Program (CACFP) regulation, 7 CFR 226.20(b)(2), “either breast milk or iron-fortified infant formula, or portions of both, must be served for the entire first year.” Any product labeled as an iron-fortified infant formula, legally must meet the Food and Drug Administration (FDA)’s definition, 21 CFR 107.10(b)(4) (i), as a product “which contains 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 can be found on the nutrition label of infant formulas.

2. Must a provider have a medical statement on file for an infant formula to be part of a reimbursable meal?

If a formula is not on the current list of the *Iron-Fortified Infant Formulas That Do Not Require a Medical Statement*, a child care provider or institution may use the following criteria to determine whether or not a formula is reimbursable under the CACFP without the need of a medical statement:

- a) Ensure that the formula is not listed as 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 (21 CFR 107.3). Formulas classified as Exempt Infant Formulas by FDA require a medical statement in order to be served to infants under the CACFP as part of a reimbursable meal. A medical statement must be signed by a licensed physician if an infant is considered disabled according to USDA’s regulation, or a recognized medical authority specified by the State agency if an infant has medical or other special dietary needs. To check

whether or not an infant formula is an FDA Exempt Infant Formula, visit FDA's website at <http://www.cfsan.fda.gov/~dms/inf-exmp.html>.

- b) Examine the nutrition label to make sure that the formula is iron-fortified. The statement "Infant Formula with Iron" or a similar statement must be on the label.
- c) Be aware of the fact that all infant formulas marketed in the United States must meet the nutrient specifications listed in FDA Regulation, 21 CFR 107 <http://www.cfsan.fda.gov/~lrd/cfr107.html#spD> and in the Section 412 of the Food, Drug, and Cosmetic Act <http://www.fda.gov/opacom/laws/fdcact/fdcact4.htm#sec412>. If a formula is purchased outside of the United States, it is likely that the formula is not regulated by FDA; therefore, it may not be creditable under the CACFP.

The nutritive values of each formula are listed on the product's nutrition label. Infant formula manufacturers may have their own proprietary formulations, but they must contain at least the minimum levels of all nutrients specified in FDA regulations without going over the maximum levels, when maximum levels are specified.

- d) Also be aware of the fact that manufacturers of infant formula are required by FDA regulation to follow current Good Manufacturing Practices, including quality control procedures to assure that the infant formula provides nutrients in accordance with Section 412 of the Food, Drug, and Cosmetic Act, and to assure that the infant formula is manufactured in a manner designed to prevent adulteration.

A child care provider can serve a formula if the exact product is on the current list of the *Iron-Fortified Infant Formulas* without the need of obtaining a medical statement.

In the memorandum from Connecticut, the issue of whether the two specific brands of infant formulas are creditable was questioned. Similac Advance is an iron-fortified infant formula that is currently included in the list of *Iron-Fortified Infant Formulas That Do Not Require a Medical Statement*. Similac Alimentum Advanced, is an infant formula that is on the FDA Exempt Infant Formula list; therefore, it is not creditable unless supported by a statement from a licensed physician or a recognized medical authority specified by the State agency, as appropriate, that indicates the need for this special formula.

If a child care provider or institution is not sure of whether or not an infant formula is creditable under the CACFP, they should contact their State agency who can contact FNS for assistance, as needed

- 3. Can you provide guidance about a formula supplied by the parent that is not iron-fortified? Would service of this product require a medical statement in order to be creditable for a reimbursable meal for an infant?**

As stated above, according to 7 CFR 226.20(b)(2), “either breast milk or iron-fortified formula, or portions of both, must be served for the entire first year.” In addition, Page 24 of *Feeding Infants: A Guide for Use in the Child Nutrition Programs*, Paragraph 2, states that low-iron formulas do not meet the meal pattern and may be served as a dietary substitution only if an infant is unable to consume iron-fortified infant formula because of medical or other special dietary needs. The substitution can only be made when supported by a statement from a licensed physician or a recognized medical authority that indicates the recommended infant formula. These rules apply to formula provided by the CACFP facility and to formula provided by the parent.

While our responses to these questions pertain to meals served to infants in the CACFP, it should be noted that they also apply to meals containing infant formula under the National School Lunch Program or the School Breakfast Program. If you have additional questions about infant formula in any of the child nutrition programs, please contact Clare Miller or Yibo Wood.

Sincerely,

A handwritten signature in dark ink, appearing to read "Stanley C. Garnett". The signature is written in a cursive style with some loops and flourishes.

STANLEY C. GARNETT
Director
Child Nutrition Division

cc: FNS Regional SNP Directors
Cheryl Fogerty, NERO