



United States  
Department of  
Agriculture

December 04, 2013

Food and  
Nutrition  
Service

**SUBJECT:** WIC Policy Memorandum #2014-1  
Changes to Abbott Infant Formula Product Line

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Alexandria, VA  
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**TO:** Regional Directors  
Special Nutrition Programs  
All Regions

WIC State Agency Directors  
All Regions

## **BACKGROUND**

On December 2, 2013, Abbott announced changes to its infant formula product line. As a result of the changes, some products will no longer meet the WIC caloric requirement.

## **PURPOSE**

The purpose of this memorandum is to remind State agencies that administer the Special Supplemental Nutrition Program for Women, Infants and Children (WIC) of the Federal WIC statutory and regulatory requirements for the authorization, issuance and rebate of infant formula in the WIC food packages.

## **ISSUANCE OF PRIMARY BRAND INFANT FORMULA**

Section 17(h)(8)(A)(v) of the Child Nutrition Act (42 U.S.C. 1786(h)(8)(A)(v)) and Federal WIC regulations at 7 C.F.R. 246.10(e)(1)(iii) require State and local agencies to issue, as the first choice of issuance, the primary contract infant formula, with all other infant formula issued as an alternative to the primary contract brand. The primary contract infant formula is suitable for routine issuance to the majority of generally healthy full-term infants.

## **MINIMUM REQUIREMENTS AND SPECIFICATIONS FOR INFANT FORMULA**

Federal WIC regulations at 246.10(e)(12) establish the minimum requirements and specifications for all WIC supplemental foods. Table 4 of this section states that infant formula must:

- (1) meet the definition for an infant formula in section 201(z) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(z)) and meet the requirements for an infant

AN EQUAL OPPORTUNITY STATEMENT

The contents of this guidance document do not have the force and effect of law and are not meant to bind the public in any way. This document is intended only to provide clarity to the public regarding existing requirements under the law or agency policies.

- formula under section 412 of the Federal Food, Drug and Cosmetic Act, as amended (21 U.S.C. 350a) and the regulations at 21 CFR parts 106 and 107;
- (2) be designed for enteral digestion via an oral or tube feeding;
  - (3) provide at least 10 mg iron per liter at standard dilution;
  - (4) provide at least 67 kilocalories per 100 milliliters (approximately 20 kcal/oz) at standard dilution; and
  - (5) not require the addition of any ingredients other than water prior to being served in a liquid state.

Based on these regulatory requirements, infant formula products that do not meet the minimum requirements and specifications generally may not be authorized for use in the WIC Program.

However, Federal WIC regulations at 246.10(d)(1)(ix) allow, at the State agency option, a **contract brand** infant formula that does not meet the requirements of Table 4 of section 246.10(e)(12) to be authorized for use with medical documentation. If this option is exercised, State agencies must issue the contract brand infant formula in amounts specified in Table 1 at section 246.10(e)(9) and adhere to the medical documentation requirements at section 246.10(d).

**States agencies may not under any circumstances authorize a non-contract brand infant formula that does not meet the Federal WIC minimum requirements and specifications.**

For assistance with infant formula issuance amounts consistent with WIC regulations, WIC State agencies may utilize the WIC Infant Formula Calculator which can be accessed via the following link: [http://wicworks.nal.usda.gov/nal\\_web/wicworks/](http://wicworks.nal.usda.gov/nal_web/wicworks/).

## **INFANT FORMULA REBATE CONTRACTS**

Pursuant to 7 C.F.R. 246.16a(c)(2), State agencies are reminded that infant formula rebate contracts require manufacturers to pay a rebate on all infant formulas it produces that the State agency chooses to issue, except exempt infant formulas. Therefore, State agencies must bill and collect a rebate for all contract brand infant formula issued, including any contract infant formula issued that requires medical documentation.

## **SUMMARY**

In summary, State agencies holding infant formula rebate contracts with Abbott should assess their options as a result of the changes to Abbott's product line. State agencies must issue as the first choice of issuance the primary contract brand infant formula to the majority of healthy full-term infants. At the State agency option, a contract brand infant formula that does not meet the minimum requirements and specifications established in Table 4 of section 246.10(e)(12) of Federal WIC regulations may be authorized for use with medical

documentation. States agencies may not under any circumstances authorize a non-contract brand infant formula that does not meet the Federal WIC minimum requirements and specifications.

Please contact your respective Regional Office with any questions about the authorization, issuance and rebate of infant formula.

A handwritten signature in black ink that reads "Debra R. Whitford". The signature is written in a cursive style with a large, sweeping initial 'D'.

DEBRA R. WHITFORD  
Director  
Supplemental Food Programs Division