

**Georgia WIC Approved Formulary****Policy No. NS- 210.20**

Effective date: October 1, 2016

No. of Pages: 3

**Policy**

The Local Agency may only authorize the issuance of formulas and nutritionals available on the [Georgia WIC Approved Formulary](#) . Exempt infant formulas and nutritionals not currently on the Georgia WIC Approved Formulary may be added to the formulary by formal request from the medical provider or other applicable party.

**Purpose**

To ensure that GA WIC participants only receive infant formula and nutritionals that meet the minimum federal requirements for WIC-eligibility.

**Procedures**

- I. Only authorize the issuance of formulas and nutritionals available on the [Georgia WIC Approved Formulary](#).
- II. Offer the comparable contract infant formula available on the [Georgia WIC Approved Formulary](#) to participants transferring from another state who are using a non-contract, milk or soy based infant formula that Georgia WIC does not approve.
- III. When a provider or participant requests an exempt infant formula or nutritional that is not currently listed on the [Georgia WIC Approved Formulary](#), contact the State WIC Office to initiate a formulary addition request. The product will be reviewed with consideration to the following:
  - A. The medical provider or applicable party must provide written documentation of participant need or a market demand for the formula or nutritional.
  - B. Documentation of USDA authorization as a WIC-eligible formula or nutritional must be on record. (This may be presented as the USDA WIC Authorization Letter or verified through the [WIC Works Formula Database](#))
  - C. The State WIC Office Nutrition Unit will review the requested product for appropriateness and accessibility.
  - D. Following review, the State WIC Office will provide notification to the requesting party of the denial or approval of any formulary additions.

Note: The timeline for requests for approvals can vary from a few days to several weeks. A more specific timeline may be provided at the time of the request.

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**Authority**

7 C.F.R. § 246.10(e)(1)(iii) 7 C.F.R. § 246.10(e)(12), Table 4

21 C.F.R. §§ 106 and 107

Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 301 *et seq*)**Definitions/Supporting Information**

**Competent Professional Authority (CPA)** – An individual on the local agency staff who is authorized to determine nutritional risk and prescribe supplemental foods. The following individuals may be authorized and trained to serve as a CPA: physicians, nutritionists (bachelor's or master's degree in Nutritional Sciences, Community Nutrition, Clinical Nutrition, Dietetics, Public Health Nutrition), registered dietitians, licensed dietitians, registered nurses, and physician assistants (certified by the National Committee on certification of Physicians Assistants or certified by the State medical certifying authority), or State or local medically trained health officials.

**Contract Infant Formula** – All infant formula (except exempt infant formulas) produced by the manufacturer awarded the infant formula cost containment contract.

**Exempt Infant Formula** – An infant formula that is intended for commercial or charitable distribution that is represented and 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).

**Infant formula** - Means a food that meets the definition of an infant formula in section 201(z) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(z)) and that meets the requirements for an infant formula under section 412 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350a) and the regulations at 21 CFR parts 106 and 107.

**Local Agency (LA)** – A public or private, nonprofit health or human service agency that provides health services, either directly or through contract.

**Non-Contract Brand Infant Formula** – All infant formula, including exempt infant formula, that is not covered by an infant formula cost containment contract awarded by the State agency and is not subject to rebates.

**WIC Eligible Nutritionals** – means certain enteral products that are specifically formulated to provide nutritional support for individuals with a qualifying condition, when the use of conventional foods is precluded, restricted, or inadequate. Such WIC-eligible nutritionals must serve the purpose of a food, meal or diet (may be nutritionally complete or incomplete) and provide a source of calories and one or more nutrients; be designed for enteral digestion via an oral or tube feeding; and may not be a conventional food, drug, flavoring, or enzyme. WIC-

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eligible nutritionals include many, but not all, products that meet the definition of medical food in Section 5(b)(3) of the Orphan Drug Act (21 U.S.C. 360ee(b)(3)).