

Issuance of Ready-to-Feed Products**Policy No. NS- 210.18**

Effective date: October 1, 2016

No. of Pages: 2

Policy

All infant formulas, exempt infant formulas, and WIC-eligible nutritionals must be issued in concentrated liquid or powder physical forms. Ready-to-feed forms may be authorized in special situations.

Purpose

To provide participants with the most cost-effective form of infant formula and nutritionals while ensuring that the option of the ready-to-feed product is accessible in situations where the powder or concentrated form is unavailable or inappropriate.

Procedures

- I. Issue ready-to-feed WIC-eligible nutritionals when the CPA or medical provider determines and documents any of the following:
 - A. The participant's household has an unsanitary or restricted water supply or poor refrigeration.
 - B. The person caring for the participant may have difficulty in correctly diluting concentrated or powder forms.
 - C. The formula is only available in a ready-to-feed form.
 - D. The issuance of nursettes is more appropriate than a larger, ready to feed alternative.
- II. Issue ready-to-feed formulas to participants with qualifying medical conditions, who are assigned to Food Package III, when the medical provider or CPA determines and documents any of the following:
 - A. The ready-to-feed form better accommodates the participant's medical condition.
 - B. The ready-to-feed form improves the participant's compliance in consuming the prescribed formula.

Authority

7 C.F.R. §§ 246.10(e)(1)(iv) and (e)(3)(iii).

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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.

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 - 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.

WIC-Eligible Nutritionals - 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-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)).

Nursette – a small bottle (two to three ounces) of ready-to-feed infant formula typically used in hospitals for newborn infants.