Procedure: Definitions of Formula Terms

Functional Area: II Nutrition Services/Breastfeeding

Section: B 4a | Approval Date: 6/19/2015

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Purpose

To provide clarification of USDA/FDA definitions of the following terms:

- Infant Formula
- Exempt infant formula
- WIC-eligible Nutritionals
- Contract brand infant formula
- Primary contract infant formula
- Non-Contract infant formula

These terms may be found in USDA correspondence, informational databases (such as WIC-WORKS website), and other areas used by State and Local agency WIC staff.

Infant Formula Definition

A food which purports to be or is represented for special dietary use solely as a food for infants by reason of its simulation of human milk or its suitability as a complete or partial substitute for human milk.

Defined in sections 201(z) and 412 of the Federal Food, Drug, and Cosmetic Act

In Nebraska WIC procedures, referred to as standard milk-based formulas, standard soy-based formulas, and modified standard milk or soy based formulas

Examples of infant formulas include (but not limited to):

Enfamil Infant
Enfamil Gentlease
Enfamil ProSobee
Enfamil A.R.

Exempt Infant Formula

Any infant formula designed for infants with special conditions such as prematurity, low birth weight, or medical conditions which require a modified infant formula. These formulas are authorized when a physician determines and documents that the participant has a medical condition that restricts the use of a conventional formula or foods and requires a special formula. A prescription from a licensed health care professional authorized to write medical prescriptions under State law is required.

Exempt Infant Formula (cont.)	Defined in sections 201(z) and 412(h) of the Federal Food, Drug, and Cosmetic Act **In Nebraska WIC procedures, referred to as special formula** Examples of exempt infant formulas (special formulas) include (but not limited to): Alimentum, EnfaCare, Neocate Similac NeoSure, EleCare, Nutramigen with Enflora
WIC-Eligible Nutritionals	Enteral products specifically formulated to provide nutrition support for individuals with a qualifying condition when use of conventional foods is precluded, restricted or inadequate (See MPSF: WC-00-25-P). Such WIC-eligible Nutritionals may be nutritionally complete or incomplete; however, they must serve the purpose of a food, provide a source of calories and one or more nutrients, and be designed for enteral digestion via an oral or tube feeding. Issuance of WIC-eligible Nutritionals must be approved by the WIC CPA and supported with a medical prescription that includes documentation of a medical condition, such as metabolic disorders, inborn errors of amino acid metabolism, gastrointestinal disorders, malabsorption syndromes, and food allergy/intolerance. **In Nebraska WIC procedures, medical foods are referred to as special formulas and/or medical/nutritional products** Examples of WIC-eligible Nutritionals include (but not limited to): Neocate One+, Vivonex Pediatric PediaSure, Nutren Jr EleCare, Peptamen Junior
Contract Brand Infant Formula	All infant formulas (excluding exempt infant formulas) produced by the manufacturer that has been awarded the infant formula rebate contract. In Nebraska, the contract infant formulas are produced by Mead Johnson.
Primary Contract Infant Formula	The primary contract infant formula is the first choice of issuance, and shall be the first formula issued to all infants. Other infant formulas may be issued in situations where an alternative is necessary. The primary contract infant formula for Nebraska WIC is Enfamil Infant. For more information on issuance of contract brand infant formulas see II B 3a.

Non-Contract Brand Formula	All infant formulas, including exempt infant formula, that are not covered by an infant formula rebate contract. Non-contract milk and soy based formulas are not issued to infants in Nebraska. Defined in USDA WIC Program Federal Regulations 246.2
Additional Information	For more information see the Formula and Medical Nutritional Product List in Appendix II B