

II. Nutrition Services

3. Food Package Section

2.3.100 Exempt Infant Formula and WIC-Eligible Nutritional Selection

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POLICY: The state agency (SA) will evaluate all exempt infant formulas and WIC-eligible nutritionals on a product-by-product basis in accordance with the selection criteria to determine approval for issuance in the Missouri WIC program.

PROCEDURE:

- A. The SA shall collect information on exempt infant formulas and shall evaluate them based on the following:
1. All exempt infant formulas must meet the requirements below:
 - a. Must be approved by the U.S. Food and Drug Administration (FDA) and meet the definition and requirements for an exempt infant formula under section 412(h) of the Federal Food, Drug, and Cosmetic Act as amended (21 U.S.C. 350a(h)) and the regulations at 21 CFR parts 106 and 107 and be designed for enteral digestion via oral or tube feeding.
 - b. Must be concentrated liquid, ready-to-feed (RTF), or reconstituted powders which are fed to infants and children with special dietary needs due to conditions including, but not limited to, premature birth, low birth weight, metabolic disorders, inborn errors of amino acid metabolism, gastrointestinal disorders, malabsorption syndromes, and severe food allergies. These products serve as substitutes for human milk.
 - c. Must not require the addition of any ingredients other than water prior to being served in a liquid state.
 - d. Must be determined WIC-eligible by USDA. Federal Regulatory requirements for WIC eligibility can be found here: [Information for Food Manufacturers](#).
- B. The SA shall collect information on WIC-eligible nutritionals and shall evaluate them based on the following:
1. All WIC-eligible nutritionals must meet the requirements below:
 - a. 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; and be designed for enteral digestion via an oral or tube feeding; and may not be a conventional food, drug, flavoring, or enzyme.

- b. Must be prescribed by a physician for a child older than 12 months of age or a woman who has special nutrient needs in order to manage a disease or health condition, except for the sole purpose of managing body weight.
- c. Must be labeled for the dietary management of a medical disorder, disease, or condition.
- d. Must be labeled to be used under medical supervision.

C. Items not allowed include:

- 1. Formulas used solely for the purpose of enhancing nutrient intake or managing body weight addressing picky eaters or used for a condition other than a qualifying condition (e.g., vitamin pills, weight control products).
- 2. Medicines or drugs.
- 3. Hyperalimentation feedings (nourishment administered through a vein).
- 4. May not be a conventional food.
- 5. Enzymes, herbs, or botanicals.
- 6. Oral rehydration fluids or electrolyte solutions.
- 7. Flavoring or thickening agents.
- 8. Feeding utensils or devices (e.g., feeding tubes, bags, and pumps) designed to administer a WIC-eligible formula.
- 9. Sports or breakfast drinks.

D. Product description and information related to the product must be reviewed thoroughly to ensure that the product is appropriate for the intended uses.

E. The WIC SA nutrition coordinator shall review the results of the product evaluation and submit recommendations to the SA WIC director for approval.

F. The SA will revise the formula reference sheet if the product is approved by the Missouri WIC program. Not all formulas meeting the requirements listed will be approved.

G. The SA WIC director will send an e-mail message to all local agencies announcing approval or non-approval of exempt infant formulas and WIC-eligible nutritionals.