

Nutrition/Health Volume
Food Package Section

Exempt Infant Formula and Medical Food Selection (2.06760)

ER# 2.06760

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POLICY: The state WIC office will evaluate all exempt infant formulas and medical foods on a product-by-product basis based on the selection criteria to determine which ones will be eligible to be issued in the Missouri WIC Program.

PROCEDURE:

- A. All exempt infant formulas for the Missouri WIC Program shall be reviewed, evaluated, and approved by the following procedures:
1. The state WIC office shall collect information on exempt infant formulas and shall evaluate them based on the following:
 - a. All exempt infant formulas must meet the requirements below:
 - i. Must be liquids or reconstituted powders which are fed to infants and children with special dietary needs due to conditions such as metabolic disorders, inborn errors of amino acid metabolism, gastrointestinal disorders, malabsorption syndromes, and food allergies. These products serve as substitutes for human milk.
 - ii. Must not require the addition of any ingredients other than water prior to being served in a liquid state.
 - iii. Must be approved by the U.S. Food and Drug Administration (FDA).
 - iv. Must be determined WIC eligible by USDA.
 - b. Product description and literature related to the new product must be reviewed thoroughly to assure that the product is appropriate for the intended uses.
 2. The state WIC office shall provide the result of the product evaluation to the state WIC nutrition coordinator for review. The recommendation for approval will be given to the WIC Director.
- B. All medical foods for the Missouri WIC program shall be reviewed, evaluated, approved by the following procedures:
1. Assigned WIC program staff shall collect information on medical foods and shall review and evaluate them based on the following:
 - a. All medical foods must meet the requirements below:
 - i. Must be designed to 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.

- ii. Must be labeled for the dietary management of a medical disorder, disease, or condition.
 - iii. Must be labeled to be used under medical supervision.
 - iv. Must be classified in one of the following categories as defined by FDA:
 - a.) Nutritionally complete formulas.
 - b.) Nutritionally incomplete formulas, including individual "modular" type products that may be mixed with other products before use.
 - c.) Formulas for metabolic (genetic) disorders in patients over 12 months of age.
 - v. Must be a food for oral or tube feeding.
 - vi. Must be determined WIC eligible by USDA.
- b. Product description and literature related to the product must be reviewed thoroughly to assure that the product is appropriate for the intended uses.
2. The results of the product evaluation shall be reviewed by the state WIC nutrition coordinator, and the recommendation for approval will be given to the WIC Director.
- C. The state WIC office will revise the formula reference sheet in coordination with the assigned WIC program staff if the product is approved by the Missouri WIC program.
- D. The WIC Director will send an e-mail message to all local WIC providers announcing approval or non-approval of exempt infant formulas or medical foods.