# **Returned Formulas and WIC-eligible Nutritionals**

Policy No. NS- 210.21

Effective date: April 1, 2019 No. of Pages: 2

## **Policy**

The local agency can only allow infant formulas and WIC-eligible nutritionals to be returned due to food package changes.

Only infant formulas and WIC-eligible nutritionals originally purchased with WIC funds can be returned.

Infant formulas and WIC-eligible nutritionals that were damaged or expired at the time of purchase, cannot be returned to the WIC clinic and must be returned to the vendor to be exchanged.

All returned infant formulas and WIC-eligible nutritionals must be tracked using the Returned Formula Tracking Log.

Returned formula must be stored in a secure location that is out of view of WIC participants. Formula must be protected from spoilage, infestation, damage or other conditions that may damage the wholesomeness or degrade the nutritional value or safety of the formula.

All returned formulas will be donated to community food programs, such as a local food bank, in the month it was received.

The local agency shall not redistribute returned infant formula or WIC-eligible nutritionals for any subsequent participant issuance.

All returned formula must be inspected for visible defects and labels checked to ensure that the "use-by-date" has not expired. In accordance with FDA rules, infant formula that is past its "use-by-date" or that is visibly dented or damaged should be discarded and must not be distributed to community food programs.

### **Purpose**

To safeguard participants against the possibility of receiving infant formulas or WIC-eligible nutritionals that may have been tampered with or improperly stored.

#### **Procedures**

- I. Advise participants to redeem small amounts of formula at a time until tolerance is confirmed, to limit the amount of returned formula.
- II. Document the details of returned formula on the Returned Formula Tracking Log.
- III. Donate returned formula to a local community food program.
  - A. Record on the <u>Returned Formula Tracking Log</u> the amount of formula donated and to which community food program.

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- IV. When formula is past the use-by-date, physically damaged, or otherwise not suitable for donation:
  - A. Dispose of returned formula by completely emptying the contents of the formula container prior to throwing it away.
  - B. Containers of powder formula should be opened and emptied into a trash receptacle, sealed, and promptly disposed of.
  - C. Containers of concentrate and ready to use formula should be opened and poured into a sink before the formula container is placed in the trash.
- V. Each time formula is donated and/or disposed of, the <u>Returned Formula Tracking Log</u> should be closed out with a signature and date. A new log is required for each donation.
- VI. Keep completed signed monthly <u>Returned Formula Tracking Log(s)</u> on file at each local agency WIC clinic.
- VII. Start new monthly Returned Formula Tracking Logs as often as needed throughout the month.

## **Authority**

USDA Special Supplemental Nutrition Program for Women, Infants and Children (WIC) Food Package Policy and Guidance March 2018.

WIC Policy Memorandum #2020-1 Donation of Unused Returned Infant Formula.

## **Definitions/Supporting Information**

**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.

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-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)).

**Community Food Program** – community-based or nonprofit food assistance programs that provide individuals with food assistance (ie. local food banks).