Returned Formulas and WIC-eligible Nutritionals

Effective date: April 1, 2019

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.

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

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.

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

All returned infant formula and WIC-eligible nutritionals not disposed of immediately, must be marked for destruction upon receipt (i.e. write or label as “discard” or “do not use” on the container).

All returned infant formula and WIC-eligible nutritionals must be disposed of in the month it was received and documented on the Returned Formula Tracking Log.

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. Dispose of returned formula by completely emptying the contents of the formula container prior to throwing it away.
   A. Containers of powder formula should be opened and emptied into a trash receptacle, sealed, and promptly disposed of.
   B. 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.

III. Document the details of returned formula and its disposal on the Returned Formula Tracking Log.
   A. Enter all returned formula on the Returned Formula Tracking Log on the day it was returned.
   B. Each time formula is disposed of, the Returned Formula Tracking Log should be
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C. Start new monthly Returned Formula Tracking Logs as often as needed throughout the month.

D. Keep completed signed monthly Returned Formula Tracking Log(s) on file at each local agency WIC clinic.

Authority


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)).