

Appendix H
WIC Policy Memo: 2023-01
Abbott Infant Formula Recall Waiver
Expiration Schedule



Food and
Nutrition
Service

DATE: November 8, 2022
SUBJECT: WIC Policy Memorandum #2023-1:
Abbott Infant Formula Recall Waiver Expiration Schedule

1320
Braddock
Place
Alexandria,
VA
22314

TO: Regional Directors
Special Nutrition Programs
All Regional Offices

WIC State Agency Directors
All WIC State Agencies

On February 17, 2022, the U.S Food and Drug Administration (FDA) announced a recall of certain Abbott powder infant formula and exempt infant formula, which exacerbated existing supply chain issues resulting from the ongoing Coronavirus Disease 2019 (COVID-19) pandemic. Immediately thereafter, the U.S. Department of Agriculture (USDA) Food and Nutrition Service (FNS) began approving State agency requests for waivers of select statutory and regulatory provisions to aid Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) participants in redeeming WIC infant formula benefits. To date, FNS has granted nearly 500 waivers to nearly all WIC State agencies.

Most recently, on August 23, 2022, FNS published WIC Policy Memorandum #2022-7, which utilized authority granted under the Access to Baby Formula Act ([PL 117-129](#), ABFA) to extend most waivers through the earlier of either December 31, 2022 or 60 days after the expiration of the COVID-19 major disaster declaration in the affected area. Currently, the COVID-19 major disaster declarations remain active for all States, Indian Tribal Organizations, and U.S. Territories under the Stafford Act pursuant to the nationwide emergency declared on March 13, 2020.

FNS recognizes that the flexibilities provided by most of these waivers remain necessary as infant formula supply chain issues continue. Further, WIC State agencies have expressed a need for advanced notice of waiver expiration. Therefore, **FNS is setting the expiration date for most waivers (see attachment) through the earlier of either January 31, 2023, or 60 days after the expiration of the COVID-19 major disaster declaration in the affected area.** FNS appreciates the extensive input State agencies have provided both through listening sessions and other informal information sharing and is taking this input under consideration as we evaluate the need for flexibilities beyond this date, particularly regarding the supply of specialty formulas.

This revised expiration schedule applies to most waiver types, including those related to medical documentation, maximum monthly allowances, vendor substitutions and imported formula authorization and issuance. Attached is a detailed list of waiver types and their expiration schedules.

USDA FNS will continue to support WIC State agencies in their efforts to ensure WIC participant access to infant formula, and recognize that the transition back to regular operations and a stable formula supply may vary across State agencies for a number of reasons. As a reminder, WIC State agencies may discontinue use of a waiver at any time by notifying their FNS Regional Office when the waiver is no longer needed. To elect one or more of the waiver types already approved by FNS, State agencies must notify their Regional Office of their decision to opt in prior to the end of the major disaster declaration in the affected area.

State agencies with questions related to this memorandum should contact their respective [FNS Regional Office](#).

Sara L Olson

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Attachment: Expiration Schedule by Waiver Type

Waiver Type	Purpose	Expiration Schedule & Rationale
Vendor Exchanges - Infant Formula	Allows stores to exchange recalled formula purchased with WIC benefits.	<i>September 30, 2022 or the expiration of the COVID-19 major disaster declaration in the affected area, whichever is earlier.</i> This waiver is no longer needed as participants no longer have recalled product on hand to exchange in a retail setting.
Medical Documentation for Food Packages I & II - Infant Formula	Allows healthy infants receiving Food Package I or II to receive a different brand of formula without a doctor's note.	<i>January 31, 2023 or 60 days after the expiration of the COVID-19 major disaster declaration in the affected area, whichever is earlier.</i> This waiver supports WIC participants in being able to purchase any infant formula (outside of the contract formula) available on the shelf.
Maximum Monthly Allowance (MMA) for Food Packages I & II - Infant Formula	Allows healthy infants receiving Food Package I or II to receive alternate container sizes, including those that are larger than usually allowed.	<i>January 31, 2023 or 60 days after the expiration of the COVID-19 major disaster declaration in the affected area, whichever is earlier.</i> This waiver provides flexibility in container size for both contract and non-contract (including imported) formula that will be needed as supply challenges continue.
Maximum Monthly Allowance (MMA) for Food Package III – Infant Formula	Allows medically-fragile infants receiving Food Package III to receive alternate container sizes, including those that are larger than usually allowed.	<i>January 31, 2023 or 60 days after the expiration of the COVID-19 major disaster declaration in the affected area, whichever is earlier.</i> This waiver provides flexibility in container size for specialty products (e.g., extensively hydrolyzed, amino-acid, or metabolic formulas) that will be needed as supply challenges continue and State agencies authorize imported infant formula.
WIC Vendor Formula Substitutions During a Transaction	Allows stores to substitute formula manually when online benefit technology is not available (i.e., offline EBT States)	<i>January 31, 2023 or 60 days after the expiration of the COVID-19 major disaster declaration in the affected area, whichever is earlier.</i> This waiver is still needed for the one offline EBT State agency using it.
Imported Infant Formula under FDA's Infant Formula Enforcement Discretion	WIC State agencies that opt into the three nationwide waivers may issue certain imported formulas. Certain specifications for infant formula (iron/kcal) are waived and a requirement for FDA registration.	<i>January 31, 2023 or 60 days after the expiration of the COVID-19 major disaster declaration in the affected area, whichever is earlier.</i> These three waivers allow WIC State agencies to authorize and issue imported infant formula.