



Food and
Nutrition
Service

DATE: August 23, 2022
SUBJECT: WIC Policy Memorandum #2022-7
Abbott Infant Formula Recall Waiver Expiration Schedules

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, including eight different waiver types, to 84 WIC State agencies.

FNS has approved five types of waivers pursuant to the authority under the Robert T. Stafford Disaster Relief and Emergency Assistance Act (42 U.S.C. 5121-5207, Stafford Act) through the earlier of September 30, 2022 or the expiration date of the COVID-19 major disaster declaration in the affected area. Additionally, FNS has granted three types of waivers pursuant to authority under the Access to Baby Formula Act ([PL 117-129](#), ABFA) through the earlier of either November 30, 2022 or 60 days after the expiration of the COVID-19 major disaster declaration in the affected area. The COVID-19 major disaster declarations are currently approved 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 December 31, 2022 or 60 days after the expiration of the COVID-19 major disaster declaration in the affected area.** In order to provide State agencies with this 60 days' notice following the expiration of the major disaster declaration in the affected area, FNS is transferring waivers originally approved under the Stafford Act to approval under ABFA. While overall infant formula supply is stabilizing, based on current data and trend analysis, FNS anticipates infant formula supply to continue to face challenges throughout the next 3-4 months due to a shift in the varieties and sizes traditionally available in the market. The December 31 expiration date will provide State agencies additional time to continue to provide flexibilities for participants who receive infant

formula benefits under WIC and plan for a transition back to normal operations. FNS will continue to monitor this dynamic situation and communicate with State agencies if there becomes a 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, imported formula authorization and issuance, and vendor substitutions. One type of waiver, for vendor exchanges, is no longer needed and will expire on September 30, 2022. 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 as they prepare for a transition back to normal operations. We also 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

SARA OLSON
Director
Policy Division
Supplemental Nutrition and Safety Programs

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>December 31, 2022 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>December 31, 2022 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>December 31, 2022 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>December 31, 2022 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.
<p>Imported Infant Formula under FDA’s Infant Formula Enforcement Discretion</p>	<p>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.</p>	<p><i>December 31, 2022 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.</p>