USDA
United States Department of Agriculture

Food and Nutrition Service

1320 Braddock Place
Alexandria VA 22314

DATE: February 18, 2022

SUBJECT: Voluntary Recall of Certain Abbott Powder Formulas, including Similac, Alimentum and EleCare

TO: Regional Directors
Special Nutrition Programs
All FNS Regional Offices

WIC State agency Directors
All WIC State Agencies

Dear WIC State Agency Directors,

On February 18, 2022, Abbott issued a voluntary recall for certain powder formulas, including Similac, Alimentum, and EleCare. Abbott is voluntarily recalling these products following an investigation by the Food and Drug Administration (FDA)(FDA Investigation of Cronobacter and Salmonella Complaints: Powdered Infant Formula (February 2022) | FDA), which included detection of *Cronobacter sakazakii*, a germ that can cause infection in infants, in environmental samples taken in Abbott's manufacturing facility in Sturgis, Michigan. Many of these products are issued by State agencies administering the Special Supplemental Nutrition Program for Women, Infants and Children (WIC Program). Consumers may visit www.similacrecall.com or call 1-800-986-8540 to determine if they have a product on hand that is included in the recall. The recall does not include soy-based infant formula, metabolic deficiency nutrition formulas, liquid infant formula or liquid exempt infant formula.

The Food and Nutrition Service (FNS) is committed to providing WIC participants with access to a variety of safe and healthy foods, including infant formula, and strongly encourages WIC State agencies to take expedient action to ensure that WIC participants can exchange recalled product on hand, and can use WIC benefits in their EBT balance or on paper WIC food instruments to purchase product that has not been recalled. FNS is committed to providing technical assistance to State agencies and maximum flexibility, including regulatory waivers (see Attachment: Process for State Agency Waiver Requests Related to Shortages) as they work with their infant formula rebate contractors and other stakeholders to respond to this recall.

FNS encourages WIC State agencies to quickly work with their legal counsel, procurement offices, and infant formula rebate contractors (e.g., Abbott Nutrition) to:

1) Determine products that may be substituted for recalled products (e.g., an identical product that has not been recalled or a different physical form or container size of the same product, a different contract brand product, or a noncontract brand product).
2) Develop processes for ensuring that all WIC participants can receive enough infant formula that has not been recalled (i.e., either by exchanging recalled product on hand, using WIC benefits to purchase product that has not been recalled, or obtaining product that has not been recalled through the State agency's home delivery or direct distribution system). See Attachment: Options for Returns and Exchanges of Recalled Product on Hand and Questions.
3) Communicate relevant information to WIC local agencies and clinics, participants, health care providers, and vendors.

For additional information from Abbott and our federal partners, please see:

- Abbott's Recall Information Site: www.similacrecall.com
- Abbott's Consumer Hotline: 1-800-986-8540
- Abbott's Press Release: Abbott Voluntarily Recalls Powder Formulas Manufactured at One Plant - Feb 17, 2022 (mediaroom.com)
- FDA Recall Information: Abbott Voluntarily Recalls Powder Formulas Manufactured at One Plant | FDA
- USDA FNS Infant Formula Safety: https://www.fns.usda.gov/ofs/infant-formula-safety
- FDA Infant Formula Safety: https://www.fda.gov/consumers/consumer-updates/infant-formula-safety-dos-and-donts
- CDC *Cronobacter* Infection and Infants: https://www.cdc.gov/cronobacter/infection-and-infants.html
- FDA Salmonella (Salmonellosis): https://www.fda.gov/food/foodborne-pathogens/salmonella-salmonellosis

As always, we thank you for your service to WIC participants and your diligence and flexibility as we navigate this unprecedented situation. Please reach out to your respective FNS Regional Office with any questions.

SARA OLSON

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Date: 2022.02.18 17:36:33 -05'00'

SARA OLSON
Acting Director
Supplemental Food Programs Division

Attachments:
Options for Returns and Exchanges of Recalled Product on Hand
Process for State Agency Waiver Requests Related to Shortages

Questions and Answers on the February 2022 Abbott Recall
Attachment: Options for Returns and Exchanges of Recalled Product on Hand

State agencies are encouraged to quickly work with their legal counsel, procurement offices, and infant formula rebate contractors to identify substitute products, as needed, and to outline and communicate to stakeholders processes for exchanges of products on hand and changing un-used benefits in participants' EBT balance or on paper WIC food instruments.

Under current regulations, State agencies are authorized to implement any of the following options for a participant to exchange recalled infant formula. State agencies must tailor these to the options determined to be available under their infant formula rebate contracts, and may tailor to any active FNS waivers. To provide maximum flexibility to respond to the recall, waivers can be requested for certain regulatory flexibilities to assist with implementing the options below. See Attachment: Process for State Agency Waiver Requests Related to Shortages.

1. Return to Vendor. WIC participants have the same rights as all other consumers under this recall. Abbott states on its website that consumers may return recalled product to the vendor where it was purchased. FNS strongly encourages State agencies to provide maximum flexibility for participants to exchange recalled product as quickly as possible, following the same procedures for all other consumers. It is not required and FNS does not recommend that WIC State agencies require vendors to determine whether a product was purchased with WIC benefits as a part of the exchange process.

2. Return to Abbott. WIC participants have the same rights as all other consumers under this recall and may follow directions from Abbott, provided via www.similacrecall.com or 1-800-986-8540 for returning recalled product.

3. Return to Clinic. The State agency may choose to allow participants to return recalled product to the clinic. The clinic may then reissue EBT benefits or paper WIC food instruments to allow WIC participants to purchase product that provides a similar reconstituted yield to the recalled product, in accordance with their rebate contract, as applicable. In replacing recalled product in a participant's EBT benefits balance (or via paper WIC food instrument), refer to the WIC Infant Formula Calculator and WIC Infant Formula Tailoring Calculator for issuing substituted product to ensure that participants receive comparable nutritive value for the replaced product.

   The following is an example of replacing Similac Advance powdered infant formula with another physical form of the same product:
   - For each 12.4 oz can powdered formula, participants should receive four (4) 13 oz. cans of liquid concentrate.

- If liquid concentrate is not available, for each 12.4 oz can of powder, participants should receive three (3) 1 qt. containers of ready-to-feed.

As a reminder, if the recalled product is an exempt infant formula, medical documentation is required for issuance of an alternative product. A health care professional licensed by the State to write prescriptions must make a medical determination and provide medical documentation that indicates the need for the appropriate formula to replace the recalled product. WIC clinic personnel should refer participants with documented qualifying conditions in need of medical care to local medical providers, as needed.

State agencies that choose to allow returns to the clinic should contact Abbott on the logistics of returning recalled product collected by WIC clinics, and should clearly and timely communicate this information with clinics. Importantly, due to safety concerns, returned infant formula involved in the recall must not be re-distributed to WIC participants or donated to food banks or food pantries.

Attachment: Process for State Agency Waiver Requests Related to Shortages

On March 13, 2020, the President declared the ongoing Coronavirus Disease 2019 (COVID-19) pandemic of sufficient severity and magnitude to warrant a nationwide emergency. The President approved major disaster declarations for the States, including Indian Tribal Organizations, and U.S. Territories pursuant to section 501(b) of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121-5207 (the "Stafford Act"). COVID-19 has resulted in nationwide supply chain issues leading to both periodic location- and product-based shortages. Because infant formulas and exempt infant formulas are already in short supply in some locations due to COVID-19, WIC State agencies may request flexibilities necessary to continue Program operations without interruption under the Stafford Act.

To request a waiver under this authority, WIC State agencies must send a formal waiver request to their FNS Regional Office that includes all of the following, for each flexibility being requested:

- The current major disaster declaration under which the request is being made (i.e., COVID-19 Major Disaster Declaration).
- The flexibility being requested (including citation).
- A brief justification for the request (e.g., "COVID-19 related shortages exacerbated by a recall have created a need for the State agency to [describe].").
- The period for which the flexibility is being requested.

Indian Tribal Organizations have the option of submitting a joint request with a geographic State agency. Infant formula rebate contract alliances may also submit joint requests. In both situations, the request must specifically state that it is being sent on behalf of multiple State agencies and must list each State agency.

A list of waivers that may be applicable in this situation is below, for consideration, and to assist State agencies in preparing waiver requests.

1. **Vendor Exchanges**
   Waive exchanges of an identical authorized supplemental food item (7 CFR 246.12(h)(3)(ii)(A)).

   WIC regulations prohibit vendors from permitting exchanges for authorized supplemental foods obtained with WIC benefits except for exchanges of an identical authorized supplemental food item (exact brand and size). To respond to shortages, WIC State agencies may request a waiver of 7 CFR 246.12(h)(3)(ii)(A) to explicitly allow vendors to exchange recalled product for the same contract brand product in a different physical form or unit size, a different contract brand product, or a noncontract brand product,

depending on options determined to be allowable under the infant formula rebate contract. If State agencies choose to allow such exchanges, they must provide clear instructions to vendors and participants.

Note: FNS does not recommend that WIC State agencies require vendors to determine whether a product was purchased with WIC benefits as a part of the exchange process.

2. Medical documentation

Waive the requirement for medical documentation for noncontract infant formula (7 CFR 246.10(d)(1)(i)) in Food Packages I and II.

WIC regulations at 7 CFR 246.10(d)(1) require medical documentation for the issuance of certain supplemental foods (e.g., noncontract brand infant formula and exempt infant formula). WIC State agencies may request from FNS a waiver of 7 CFR 246.10(d)(1)(i) to allow the State agency to waive the requirement for medical documentation for the issuance of noncontract brand infant formula. FNS will only consider requests for infant formula provided to healthy infant participants receiving Food Package I and II.

FNS will not consider waivers related to medical documentation required for any other supplemental foods outlined at 7 CFR 246.10(d)(1)(ii)-(vi). Due to the nature of the health conditions of participants who are issued supplemental foods that require medical documentation, close medical supervision is essential to determine the assessed nutritional needs for each participant's dietary management. The responsibility remains with the participant's health care provider for this medical oversight and instruction. This responsibility cannot be assumed by WIC staff.

3. Maximum Monthly Allowance (MMA)

Waive the MMA requirement for infant formula in Food Packages I and II (7 CFR 246.10(e)(9)).

WIC State and local agencies are responsible for ensuring that infant formulas are issued in amounts consistent with WIC regulations. Table 1 of 7 CFR 246.10(e)(9) establishes the MMA of reconstituted fluid ounces of liquid concentrate, ready-to-feed, and powder infant formula for each infant food package and infant feeding option (i.e. partially breastfed and fully formula fed). Only infant formula may be issued for infants in Food Packages I and II. WIC staff tailor the amount of the infant formula based on the assessed nutritional needs of the participant. FNS will only consider requests for infant formula provided to healthy infant participants receiving Food Package I and II.

Note: FNS will consider waiver requests to authorize and issue formula containers in sizes that, when added together, most closely provide the maximum monthly allowance. For example, FNS would consider requests to issue the equivalent of one container above the MMA.

Attachment: Questions & Answers on the February 2022 Abbott Recall

1) Q: Why is infant formula being recalled?

   Answer: Abbott is voluntarily recalling powder formulas, including Similac, Alimentum and EleCare manufactured in Sturgis, MI after four consumer complaints related to *Cronobacter sakazakii* or *Salmonella* Newport in infants who had consumed powder infant formula manufactured in this facility.

   For more information, visit: FDA Investigation of Cronobacter and Salmonella Complaints: Powdered Infant Formula (February 2022) | FDA

2) Q: What is *Cronobacter sakazakii*?

   Answer: *Cronobacter sakazakii*, is a bacteria (germ) found naturally in the environment. It can live in dry foods, such as powdered infant formula, powdered milk, herbal teas, and starches. *Cronobacter* can cause diarrhea and urinary tract infections in people of all ages, but infection can be very serious in infants.

   To ensure the safety of infant formula, FDA requires that manufacturers test for *Salmonella* and *Cronobacter*, two bacteria that can cause severe illness in infants.

3) What should WIC State agencies do regarding product substitutions under infant formula rebate contracts?

   Answer: WIC State agencies should work with their legal counsel, procurement offices, and infant formula rebate contractors to determine products that may be substituted for recalled products (e.g., an identical product that has not been recalled or a different physical form or container size of the same product, a different contract brand product, or a noncontract brand product).

   FNS recommends that State agencies establish regular communications with their manufacturers throughout this recall to understand the timeframes, products, and locations related to any recalls, as well as any shortages that may result, and to address localized issues as they arise.

4) What should State agencies tell participants about their infant formula benefits?

   Answer: State agencies must advise participants not to purchase or use recalled product, and how to determine whether they have already purchased recalled formula (i.e., visit www.similacrecall.com or call 1-800-986-8540). The State agency must also provide instructions to participants explaining how to receive updated WIC benefits via their EBT

cards or WIC paper food instruments, if needed, as well as how to exchange any recalled product on hand. These instructions must be consistent with the options provided by Abbott and selected by the WIC State agency (i.e., return to vendor, Abbott, or clinic).

5) What should local agencies and clinics do with formula on hand or in stock?

Answer: State agencies must advise their local agencies and clinics to check their inventories for any recalled product, including sample sized product. State agencies should contact Abbott for direction on how to return the product to Abbott. Importantly, due to safety concerns, returned infant formula involved in the recall must not be redistributed to WIC participants or donated to food banks or food pantries.

6) What flexibilities do State agencies have when determining the quantity of formula to issue?

Answer: FNS strongly encourages State agencies to provide maximum flexibility for participants to exchange recalled product as quickly as possible. Per the WIC Food Package Policy and Guidance, State agencies must issue formulas per the method (i.e., monthly issuance or use of rounding up methodology) that provides the Full Nutrition Benefit (FNB) without exceeding the maximum monthly allowance (MMA) for the physical form. State agencies must determine which method (i.e., monthly issuance or use of rounding up methodology) they will use to provide the FNB without exceeding the MMA for WIC formulas. If State agencies choose rounding, they must follow the methodology outlined at 246.10(h). WIC State agencies may request a waiver related to MMA for infant formula issued to participants in Food Package I and II (please see Attachment: Process for State Agency Waiver Requests Related to Shortages).

The WIC Formula Calculator and WIC Infant Formula Tailoring Calculator (Tailoring Calculator) can assist with determining infant formula issuance amounts within WIC regulations. These calculators differ in that the Tailoring Calculator helps a WIC Competent Professional Authority determine infant formula issuance amounts for a *particular infant* (i.e., individually tailor), whereas the WIC Infant Formula Calculator helps a WIC agency determine infant formula issuance amounts *per infant feeding category* (i.e., partially breastfed or fully formula fed) and food package time frame (e.g., 0-3 months, 4-5 months, etc.).

7) What flexibilities do State agencies have when establishing and monitoring Minimum Stocking Requirements (MSR)?

Answer: WIC State agencies may refine or update their MSR as long as the stocking thresholds remain above the federal minimums established at 7 CFR 246.12(g)(3)(i) (i.e., two different fruits, two different vegetables, and at least one whole grain cereal authorized by the State agency). State agencies may update their policies and procedures to include information on how they will respond to statewide shortages or disasters. This could include developing alternative MSR for use during certain timeframes (including policies/procedures for

implementation) and/or for when and how they will assess applicant and current vendors for MSR.

While State agencies must assess a vendor or vendor applicant for meeting the applicable MSR at initial authorization or reauthorization (7 CFR 246.12(g)(3)), they can choose to postpone periodic assessments of vendor compliance with the selection criteria during a disaster/public health emergency or other issue resulting in shortages. FNS recommends State agencies work proactively with vendors to ensure that WIC participants can access their supplemental foods.

As always, if a State agency's MSR or other vendor selection criteria are governed by its State administrative code, the State agency should work with its legal counsel to understand the flexibilities available.

Please refer to the Vendor Management & Food Delivery Handbook, (pg. 16-18) which provides even more detail about the flexibilities State agencies have when establishing MSR.

8) What should State agencies do if they provide infant formula directly to participants?

Answer: State agencies that use a Direct Distribution or Home Delivery system for infant formula must work with their contractors to identify and appropriately return any stock involved in the recall and obtain unrecalled product from their contractor. State agencies must also inform participants how to exchange infant formula on hand.

As a reminder, any State agency that purchases from the manufacturer and distributes formula out of a clinic operates a direct distribution food delivery system and must include this information in its State Plan. Note that if a State agency is paying first to ship the formula to the clinic and then to ship the formula to the participant, the second act of shipping is not an allowable cost under 7 CFR 246.14(b)(1)(i).

Distributing samples that are provided free to the State agency during COVID-19 related shortages, as a courtesy from the manufacturer are not considered a part of any food delivery system.