Food and Nutrition Service

1320 Braddock Place Alexandria, VA 22314 July 27, 2022

SUBJECT: Request for Additional WIC Flexibility in Response to the Impact of the

Ongoing Coronavirus Disease 2019 (COVID-19) Pandemic and 2022 Abbott Recall on Nationwide Infant Formula Supply Chain Issues for Infants in Food

Packages III- Maximum Monthly Allowance

TO: All FNS Regional Offices

All WIC State agencies

This letter is in response to correspondence from WIC State agencies requesting flexibility with regard to the maximum monthly allowance (MMA) requirements in the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) as a result of the impact of the ongoing Coronavirus Disease 2019 (COVID-19) pandemic and the 2022 Abbott recall of certain powder infant formula on the nationwide supply chain leading to both periodic location and product-based WIC infant formula shortages.

Applicable WIC State agencies individually requested waivers of WIC regulations at 7 CFR 246.10(e)(9), Table 1, which set forth MMA requirements for issuance of WIC infant formula issued per medical documentation to participants receiving Food Package III. These State agencies cited significant impacts on the ability of participants to obtain contract brand infant formula due to low stock during the 2022 Abbott recall of certain powder infant formula compounded by supply chain disruptions. USDA Food and Nutrition Service (FNS) understands that replacing a recalled product within existing regulatory flexibilities in amounts consistent with WIC regulations is not feasible as State agencies quickly respond to the COVID-19 related nationwide infant formula supply chain issues that have been exacerbated by this recall. A waiver to provide administrative flexibility for infants in Food Package III to exceed the MMA removes a requirement that under current circumstances could prevent or impede the provision of essential Program services to participants.

Pursuant to the authority granted under the Robert T. Stafford Disaster Relief and Emergency Assistance Act (42 U.S.C. 5121-5207), FNS approves this waiver request for WIC State agencies listed in the attachment through the earlier of either **September 30, 2022** or the expiration date of the major disaster declaration in the affected area.

This waiver is only applicable to regulations at:

• 7 CFR 246.10(e)(9), which requires a maximum monthly allowance (MMA) for infant formula. This includes 7 CFR 246.10(e)(9) Table 1 footnote 7, which requires State agencies to issue containers that are all the same size of the same physical form.

Under this waiver, the State agency must authorize and issue WIC Formula containers in sizes that provide the full nutrition benefit and most closely provide the amount prescribed per medical documentation and the maximum monthly allowance.

This approval does not waive regulatory requirements for: (1) 7 CFR 246.10(d)(1), which require medical documentation for the issuance of any supplemental food issued to participants in Food Package III, including WIC Formula; (2) 7 CFR 246.10(d)(4), which defines the technical requirements of medical documentation; (3) 7 CFR 246.10(d)(5), which prohibits WIC staff from assuming medical oversight and instruction for participants receiving supplemental foods that require medical documentation; and (4) 7 CFR 246.10(e)(3)(i), which defines the qualifying conditions for issuance of a WIC formula in food package III.

Following receipt of this waiver, the State agency will need to inform WIC staff, vendors and participants that substitutions should be made when the prescribed benefit is unavailable for purchase. The State agency must ensure participants receive clear instruction on how to select the correct number of containers of the prescribed WIC fomula in the authorized sizes each month.

Unless a State agency has additional active FNS waivers, all other federal WIC requirements must be met. WIC state agencies must work with their legal counsel, procurement offices, and infant formula rebate contractors, as appropriate.

USDA FNS appreciates the WIC State agency's commitment to quickly responding to the COVID-19 related nationwide supply chain issues that have been exacerbated by this recall.

Sincerely,

DIANE KRIVISKI

Associate Administrator

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Supplemental Nutrition and Safety Programs

Attachment:

List of WIC State agencies that have been granted an FNS waiver for: Request for Additional WIC Flexibility in Response to the Impact of the Ongoing Coronavirus Disease 2019 (COVID-19) Pandemic and 2022 Abbott Recall on Nationwide Infant Formula Supply Chain Issues for Infants in Food Packages III—Maximum Monthly Allowance