Food and Nutrition Service

1320 Braddock Place Alexandria, VA 22314 June 15, 2022

SUBJECT: Additional WIC Flexibilities in Response to the Impact of the Ongoing

Coronavirus Disease 2019 (COVID-19) Pandemic on Nationwide Infant Formula Supply Chain Issues and 2022 Abbott Recall – Imported Infant Formula under

FDA's Infant Formula Enforcement Discretion

TO: All FNS Regional Offices

All WIC State agencies

This letter provides WIC State agencies flexibility related to Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) Federal requirements. The flexibilities are being provided due to the impact of the ongoing Coronavirus Disease 2019 (COVID-19) pandemic and the resulting major disaster declarations, which exacerbated the 2022 Abbott recall of certain powder infant formula and exempt infant formula on the nationwide supply chain. USDA is collaborating across a number of government agencies to ensure that WIC participants are able to obtain safe formula.

To this end, USDA waives for all State agencies the requirements below, pursuant to the waiver authority granted under the Access to Baby Formula Act of 2022 (P.L. 117-129), providing USDA with waiver authority during a major disaster declaration. This approval applies to all State agencies that elect to use it, without further application. If the State agency elects to implement these flexibilities, it must notify its respective FNS Regional Office, which will acknowledge receipt. These waivers will remain in effect through November 30, 2022, or 60 days after the expiration of the major disaster declaration in the affected area, whichever is sooner.

These waivers allow WIC State agencies to authorize and issue certain infant formulas imported under the U.S. Food and Drug Administration's (FDA) <u>Infant Formula Enforcement Discretion Policy</u>. These waivers are necessary to provide assistance and do not substantially weaken the nutritional quality of supplemental foods provided by the WIC Program. In addition, they waive statutory and regulatory provisions that cannot be met under the conditions that prompted the major disaster declaration.

Under the FDA's Infant Formula Enforcement Discretion policy, infant formula that is safe and nutritionally adequate may be introduced into interstate commerce, even if it does not comply with all of FDA's statutory and regulatory requirements. Additionally, these infant formulas might not all meet federal WIC requirements. Therefore, the waivers listed below are necessary for WIC State agencies to authorize and issue these safe and nutritionally adequate products within the WIC Program.

The waivers/modifications being granted via this letter include:

• 42 USC 1786(f)(15)(A), 42 U.S.C. 1786 (h)(8)(ix)(II), 7 CFR 246.10(g), and 7 CFR

246.12(g)(10) which require that infant formula issued by WIC State agencies is only obtained from manufacturers registered with the FDA.

• 7 CFR 246.10(e)(12) minimum requirements and specifications for infant formula.

The waiver of this provision only applies to the minimum requirements and specifications for iron and caloric content, and may only be used to authorize and issue products that have an iron level of at least 0.6 mg/100 mL and an energy level of at least 19 kcal/oz.

These waivers only apply to infant formula being imported under FDA's enforcement discretion, as a result of the 2022 Abbott recall of certain powder infant formula and exempt infant formula during COVID-19 supply chain issues. Unless a State agency has additional active FNS waivers, all other federal WIC requirements must be met. WIC State agencies should work with their legal counsel, procurement offices, and infant formula rebate contractors, as appropriate.

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

Sincerely,

DIANE
KRIVISKI
Digitally signed by DIANE
KRIVISKI
Date: 2022.06.02
17:17:54 +04'00'

DIANE KRIVISKI Associate Administrator Supplemental Nutrition and Safety Programs

List of WIC State agencies that have elected the waivers for:

Additional WIC Flexibility in Response to the Impact of the Ongoing Coronavirus Disease 2019
(COVID-19) Pandemic on Nationwide Supply Chain Issues – Imported Infant Formula under FDA's Infant Formula Enforcement Discretion

List of WIC State agencies that have elected the waivers for:

Additional WIC Flexibility in Response to the Impact of the Ongoing Coronavirus Disease 2019 (COVID-19) Pandemic on Nationwide Supply Chain Issues – Imported Infant Formula under FDA's Infant Formula Enforcement Discretion

Elected June 22, 2022

Michigan WIC

Elected June 14, 2022

Inter-Tribal Council of Nevada WIC

Elected June 10, 2022

Illinois WIC
Three Affiliated Tribes WIC

Elected June 9, 2022

Georgia WIC Mississippi Band of Choctaw Indians WIC Northern Arapaho WIC Wyoming WIC

Elected June 8, 2022

Commonwealth of the Northern Mariana Islands WIC
Eastern Shoshone Tribe WIC
Guam WIC
Kentucky WIC
Missouri WIC
New Mexico WIC
Santee Sioux Nation WIC
Standing Rock Sioux Tribe WIC

Elected June 7, 2022

Indiana WIC Nevada WIC Utah WIC

Elected June 6, 2022

Colorado WIC Florida WIC Kansas WIC Montana WIC Nebraska WIC

Omaha Nation WIC

South Dakota WIC

Texas WIC

Wisconsin WIC

Elected June 3, 2022

Alaska WIC

American Samoa WIC

Arizona WIC

California WIC

Cherokee Nation of Oklahoma WIC

Chickasaw Nation WIC

Choctaw Nation of Oklahoma WIC

Citizen Potawtomi Nation WIC

Connecticut WIC

Delaware WIC

District of Columbia WIC

Five Sandoval Indian Pueblos Inc. WIC

Hawaii WIC

Idaho WIC

Iowa WIC

Inter-Tribal Council of Arizona WIC

Inter-Tribal Council of Oklahoma WIC

Louisana WIC

Massachusetts WIC

Minnesota WIC

Muscogee (Creek) Nation WIC

Navajo Nation WIC

New Hampshire WIC

New York WIC

North Carolina WIC

Ohio WIC

Oklahoma WIC

Osage Nation WIC

Otoe-Missouria WIC

Pennsylvania WIC

Pueblo of Zuni WIC

Rhode Island WIC

South Carolina WIC

Tennessee WIC

Ute Mountain Ute Tribe WIC

Vermont WIC

Virginia WIC Winnebago Tribe WIC

Elected June 2, 2022

Oregon WIC Washington WIC