



February 12, 2024

Administrator Cindy Long  
Food & Nutrition Service  
U.S. Department of Agriculture  
1320 Braddock Place 4th floor.  
Alexandria, VA 22314

Re: [RIN 0584-AE94](#), Special Supplemental Nutrition Program for Women, Infants, and Children (WIC): Implementation of the Access to Baby Formula Act of 2022 and Related Provisions

Dear Administrator Long:

The Asthma and Allergy Foundation of America (AAFA) is the leading patient organization for people with asthma and allergies and the oldest asthma and allergy patient group in the world. On behalf of AAFA, I am writing in support of the final rule with comments regarding WIC implementation of the Access to Baby Formula Act, and to urge USDA conduct an evaluation of formula access for babies and children with food allergies or other medical needs.

AAFA appreciates the USDA's codification of its new waiver authorities, as well as the requirements that states include provisions regarding disruptions in their contracts and state plans. We understand that the final rule will be effective on February 12, and support this swift action to move forward and proactively protect access to formulas.

We also urge USDA to take further action to assess how the 2022 formula shortage, as well as more recent problems such as the December 31 [recall of Nutramigen](#),<sup>1</sup> and the issues leading to the recent warning letters sent by FDA to three manufacturers,<sup>2</sup> may impact WIC recipients with food allergies or other

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<sup>1</sup> CBS News, "U.S.: Thousands of baby formula cans recalled after contamination found, FDA says." (Jan 2, 2024). Available at <https://www.cbsnews.com/news/nutramigen-baby-formula-recalled-possible-bacterial-contamination-reckitt-mead-johnson/>

<sup>2</sup> U.S. Food and Drug Administration, "FDA Issues Warning Letters to Three Infant Formula Manufacturers" (Aug. 30, 2023). Available at <https://www.fda.gov/news-events/press-announcements/fda-issues-warning-letters-three-infant-formula-manufacturers>



medical nutritional needs. In particular, it is important to understand whether the flexibilities that allowed WIC enrollees to purchase alternate sizes, forms, or brands of infant formula using their WIC benefits were sufficient to address the needs of these recipients. We also urge USDA to collect information about whether these families have been able to consistently access specialized formulas now that many of these flexibilities have lapsed, and if the newly-codified waiver authorities under the new final rule will suffice to address their needs.

Our concerns are detailed below.

### **The Impact of the Shortage on Families of Children with Food Allergies**

Childhood food allergies are a significant public health issue resulting in relatively high rates of severe allergic reactions and Emergency Department use. About 3% of infants and almost 9% of 1-year-olds are allergic to at least one food.<sup>3</sup> Allergic reactions can cause discomfort, impact sleep and growth; or can be severe and potentially life-threatening anaphylaxis.<sup>4</sup>

Babies who are allergic to components of mainstream infant formula, such as milk or soy, require specialized formula in order to get adequate nutrition without risking a life-threatening allergic reaction. Children with cow's milk protein allergy (CMPA) have only a few safe formula options:

- Extensively Hydrolyzed Formulas (e.g., Enfamil® Nutramigen®, Enfamil® Pregestimil®, Similac® Alimentum® or Similac® Expert Care®)
- Amino Acid-Based Formulas (e.g., Neocate®, EleCare®, PurAmino™, Alfamino™)

When these special formulas for food allergies become scarce, babies' lives and health are put at risk. While many healthy, full-term babies can, if necessary,

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<sup>3</sup> Gupta RS, Warren CM, Smith BM, et al. The public health impact of parent-reported childhood food allergies in the United States. *Pediatrics*. 2018;142(6):e20181235. doi:10.1542/peds.2018-1235

<sup>4</sup> Asthma and Allergy Foundation/Kids with Food Allergies, "Food Allergy and Anaphylaxis in Infants and Toddlers" [webinar slides]. Available at <https://www.kidswithfoodallergies.org/media/3330/aaafa-kfa-webinar-food-allergyand-anaphylaxis-in-infants-and-toddlers.pdf>



switch from brand to brand of formula, for babies with food allergies no safe alternative may be available.

The impact goes beyond babies: children and adults with eosinophilic esophagitis (EoE) are also at risk during a shortage. EoE is a type of food allergy that affects the esophagus and a person's ability to eat. Amino acid formulas like EleCare® prescribed by a doctor may be a patient's sole source of nutrition and are considered "medical foods" – nutrition products that are made to manage a disease or condition.

As detailed in our May 2022 letter (attached), many families navigating food allergies or metabolic disorders struggled to access appropriate formulas through the course of the recent shortage.

### **The flexibilities granted during the shortage were important**

As you know, since 1989, Congress has required WIC state agencies to competitively solicit bids from infant formula manufacturers to supply and provide a rebate for each can of formula purchased with WIC benefits.<sup>5</sup> The WIC state agency then awards a single-supplier contract to the manufacturer offering the highest discount on wholesale prices. Typically, WIC enrollees can only use their benefits to purchase specific sizes and forms of formula manufactured by their state's single-supplier. Those who need specific formulas for allergy or other medical reasons can access it with their WIC benefits, even if not produced by the manufacturer contracted by the state.

After the shortage began in 2022, USDA reached out to states to offer support and [announced](#) a suite of [flexibilities](#), such as allowing states to broadly permit the use of WIC benefits for alternate sizes, forms, and brands of formula.<sup>6</sup> Over 2023,

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<sup>5</sup> U.S. Department of Agriculture Food and Nutrition Service, "WIC Eligibility Requirements to Bid on State Agency Infant Formula Contracts" (updated Dec. 14, 2023). Available at <https://www.fns.usda.gov/wic/requirements-infant-formula-contracts>

<sup>6</sup> For an overview of these flexibilities and other related actions, see U.S. Department of Agriculture Food and Nutrition Service, "USDA Extends Flexibility that's Helping Manufacturers, States get Formula to WIC Families" (Sep. 1, 2022). Available at <https://www.usda.gov/media/press-releases/2022/09/01/usda-extends-flexibility-thats-helping-manufacturers-states-get>



those flexibilities were phased out,<sup>7</sup> but the new final rule codifies USDA's ability to allow such waivers in times of supply disruption.

### **Request for evaluation**

As FDA continues to address manufacturing safety and we await the results of the NASEM study on the infant formula supply,<sup>8</sup> we believe that USDA should carefully assess how WIC functioned during the shortage for families managing food allergies or other medical conditions. We urge the USDA to undertake an assessment to identify:

1. Whether the WIC program's flexibilities with regard to form, size, and type of formula were sufficient to meet the needs of recipients with food allergies or other special nutritional needs.
2. Whether beneficiaries with food allergies are currently receiving access to their needed products regardless of manufacturer, as required by law.
3. Whether further flexibilities may be warranted, either for beneficiaries with food allergies and other special needs or for a broader subset of beneficiaries, to ensure that transient or localized shortages of formula do not create gaps in access. In particular, it is important to understand if the situations permitting USDA to exercise waiver authority under the new law and regulations extend to supply disruptions that may only, or disproportionately, impact families who depend on allergenic or other exempt formulas.

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<sup>7</sup> U.S. Department of Agriculture Food and Nutrition Service, "WIC Policy Memorandum #2023-3 Unwinding Infant Formula Flexibilities in WIC" (Feb. 1, 2023). Available at <https://www.fns.usda.gov/wic/policy-memorandum-2023-3-unwinding-infant-formula-flexibilities>

<sup>8</sup> U.S. Food and Drug Administration, "FDA Announces National Academies Study of Supply, Market Competition, and Regulation of Infant Formula in the U.S." (May 19, 2023). Available at <https://www.fda.gov/food/cfsan-constituent-updates/fda-announces-national-academies-study-supply-market-competition-and-regulation-infant-formula-us>



Asthma and Allergy  
Foundation of America

We would be happy to work with the USDA to continue to share our community's experience. Please do not hesitate to reach me at [kmendez@aafa.org](mailto:kmendez@aafa.org).

Sincerely,

Kenneth Mendez  
President and Chief Executive Officer  
Asthma and Allergy Foundation of America