UNITED STATES FOOD & DRUG ADMINISTRATION

OMB Control No. 0910-0256 –

Infant Formula Requirements and Exempt Infant Formula

REQUEST FOR NON-MATERIAL CHANGE:

Background –

The referenced information collection supports implementation of statutory and regulatory authorities that govern infant formula. Specifically, 21 CFR part 106 prescribes the steps manufacturers must take under section 412(b)(2) and (b)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350a(b)(2) and (b)(3)) in *processing* infant formula. If the *processing* of the formula does not comply with any of the applicable regulations, the infant formula will be deemed to be **adulterated** under section 412(a)(3) of the Federal Food, Drug, and Cosmetic Act. Regulations 21 CFR part 107 sets forth the *labeling* requirements applicable to infant formula under section 403 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C 343). Failure to comply with any of the applicable regulations will render an infant formula **misbranded** under section 403 of the Federal Food, Drug, and Cosmetic Act.

In early 2019, with the onset of the COVID-19 Public Health Emergency (PHE), FDA began modifying the information collection by expanding the scope of activity and accounting for activity attendant to exempt infant formula regulations in 21 part 107, along with the associated guidance document, "*Exempt Infant Formula Production: Current Good Manufacturing Practices (CGMPs),*" (April 2016). Next in 2022, subsequent to the 2021 renewal cycle, we revised the information collection as part of the Federal government's response to address ongoing *disruptions in the infant formula supply*. We communicated our initial efforts to address the infant formula shortage in the May 2022 guidance document "*Infant Formula Enforcement Discretion Policy: Guidance for Industry*" (Enforcement Discretion Guidance); and clarified whether products currently subject to FDA's current enforcement discretion policy would be able to remain on the market in the guidance document, "*Infant Formula Transition Plan for Exercise of Enforcement Discretion: Guidance for Industry*" (Infant Formula Transition Plan Guidance). We also communicated efforts to leverage information already received for products over which we are temporarily exercising enforcement discretion (see Section III, Guiding Principles (p. 6)).

In December 2022, continuing efforts to protect infants and improve formula supply, the *Consolidated Appropriations Act, 2023* (Pub. Law 117-328) – Sec. 3401 provided for premarket submissions to FDA to address shortages. Specifically, at section 3401(g)(5), the statute provides for guidance regarding information sponsors may consider including in submissions as required under section 412 of the FD&C Act . Currently we communicate on our website at https://www.fda.gov/food/infant-formula-guidance-documents-regulatory-information/regulations-and-information-manufacture-and-distribution-infant-formula#export, that persons responsible for the manufacture or distribution of infant formula will be able to

submit their registration and submission of information electronically in the future. As we announced officially on our website at www.fda.gov on October 1, 2024, FDA continues to undergo an agency-wide *reorganization* that began in 2022. Currently, however, submissions may be directed in writing to:

Infant Formula and Medical Foods Staff (HFS-850)
Office of Nutrition and Food Labeling
Food and Drug Administration
5001 Campus Drive
College Park, MD 20740-3835

Accordingly, we developed the draft guidance document entitled, "*Notifying the Food and Drug Administration of a Permanent Discontinuance in the Manufacture or an Interruption of the Manufacture of an Infant Formula*," (*Shortages Guidance*) (December 2024) and are inviting public comment under both our Good Guidance Practice regulations in 21 CFR 10.115, as well as the PRA provisions in 5 CFR 1320.8(d). See 89 FR 96261.

Action Requested:

We are requesting to expand the scope of the information collection to include the statutory authority introduced under Pub. Law 117-328 and are planning to request any corresponding burden adjustment upon our submission to OMB under 5 CFR 1320.10 of the *Shortages Guidance* prior to finalization.

Relatedly, we are also requesting to include the guidance document entitled, "Protein Efficiency Ratio (PER) Rat Bioassay Studies to Demonstrate That a New Infant Formula Supports the Quality Factor of Sufficient Biological Quality of Protein" among the related supporting material for the information collection. Specifically, regulations in 21 CFR 106.96(f) describe how an infant formula manufacturer must demonstrate that a formula meets the PER quality factor criteria. We developed the guidance document to help manufacturers and laboratories in the design, conduct, evaluation, and reporting of PER studies. The guidance is intended to explain how the PER study can be used to provide assurance that a new infant formula complies with current requirements, however we have made no adjustment to our currently approved burden estimate believing this task already falls within the scope of activity.

December 2024