UNITED STATES FOOD & DRUG ADMINISTRATION

OMB Control Nos. 0910-0256 – Infant Formula Requirements; and
OMB Control No. 0910-0811 – Exempt Infant Formula

REQUEST FOR NON-MATERIAL CHANGE and DISCONTINUATION:

Justification

The referenced information collections support Food and Drug Administration (FDA) regulations and associated guidance regarding 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.

Relatedly, 21 CFR part 107 sets forth the labeling requirements applicable to infant formula under section 403 of the Federal Food, Drug, and Cosmetic 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. Information collection provisions supporting these regulations (21 CFR parts 106 and 107) are currently approved under OMB Control No. 0910-0256, which expires May 31, 2021

While the infant formula regulations help ensure the consistent production of safe and nutritionally adequate infant formulas for healthy, term infants, they apply with one narrow exception. Section 412(h)(1) of the FD&C Act exempts an infant formula represented and labeled for use by an infant with an inborn error of metabolism, low birth weight, or who otherwise has an unusual medical or dietary problem from the requirements of sections 412(a), (b), and (c) of the FD&C Act. These formulas are customarily referred to as "*exempt infant formulas*." Section 412(h)(2) of the FD&C Act authorizes us to establish terms and conditions for the exemption of an infant formula from the requirements of sections 412(a), (b), and (c) of the FD&C Act. Although certain terms and conditions are set forth in 21 CFR 107.50, we intend to promulgate regulations to address any new terms and conditions for exempt infant formulas in future rulemaking.

Until then, we have issued the agency guidance document entitled, "*Exempt Infant Formula Production: Current Good Manufacturing Practices (CGMPs), Quality Control Procedures, Conduct of Audits, and Records and Reports*." The guidance document includes our recommendation that manufacturers of exempt infant formulas follow, to the extent practicable, subparts A, B, C, D, and F of 21 CFR part 106. Burden attributable to recommendations found in the guidance are currently approved under OMB Control No. 0910-0811, which expires March 31, 2019.

Upon preparing our submission request to renew 0910-0811, a closer evaluation suggests that the information collection may be consolidated into 0910-0256. Specifically, we request consolidating the following IC into Control No. 0910-0256 and discontinuing Control No. 0910-0811:

NEW IC	No. of respondents	No. of records per respondent	Total annual	Burden per recordkeeping	Total hours
Exempt infant formula production; GMP; audits, recordkeeping, & reports	3	634.3	1903	45 hours	85,889.64

Since establishing the latter information collection in 2016 we have increased the burden estimate we attribute to recordkeeping associated with exempt infant formulas. However, in accordance with 5 CFR 1320.8(d), we published both a 60-day and 30-day notice in the Federal Register (83 FR 49393 and 84 FR 7381, respectively) requesting public comment regarding the associated burden. As yet, no comments have been received. But because the recordkeeping described in the guidance reflects recordkeeping set forth in the regulations, we believe it is appropriate to consolidate them into one collection. Additionally, we believe consolidation minimizes the chance of duplicative information collection. Finally, since last approval of 0910-0811, there have been no program changes affecting the information collection nor changes to the guidance document.

March 2019