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4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-3490]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Exempt Infant Formula Production: Current Good Manufacturing Practices, Quality Control Procedures, Conduct of Audits, and Records

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202-395-7285, or emailed to oira_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0811. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-3794, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Exempt Infant Formula Production: Current Good Manufacturing Practices (CGMPs), Quality Control Procedures, Conduct of Audits, and Records

OMB Control Number 0910-0811--Extension

Section 412(h)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 350a(h)(1)) exempts an infant formula that is 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 section 412(a)-(c) of the FD&C Act. These formulas are customarily referred to as "exempt infant formulas." Under part 106 (21 CFR part 106), we established requirements for quality factors for infant formulas and CGMPs, including quality control procedures. This collection of information will help prevent the manufacture of adulterated infant formula, ensure the safety of infant formula, and ensure that the nutrients in infant formula are present in a form that is bioavailable.

In the *Federal Register* of April 15, 2016 (81 FR 22174), we published a notice of availability for the guidance document entitled "Guidance for Industry: Exempt Infant Formula Production: Current Good Manufacturing Practices (CGMPs), Quality Control Procedures, Conduct of Audits, and Records and Reports." The guidance describes our current thinking on the manufacturing of exempt infant formula in relation to the requirements in part 106 for CGMPs, quality control procedures, conduct of audits, and records and reports that apply to nonexempt infant formulas. Persons with access to the internet may obtain the guidance at https://www.fda.gov/FoodGuidances.

Our estimate of the burden of the recordkeeping recommendations includes the one-time burden of developing production and in-process control systems and the annual burdens of developing and maintaining aggregate production and control records, records pertaining to the distribution of infant formula, and records pertaining to regularly scheduled audits. Included in the burden estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

The guidance recommended, to the extent practicable, that respondents include records required by part 106, subparts A, B, C, D, and F for non-exempt infant formulas. Because the records and reporting requirements related to part 106, subparts E and G are not generally applicable to exempt infant formula manufacturers, FDA is not recommending in the guidance that exempt infant formula manufacturers follow these requirements. As such, the records and reporting requirements in part 106, subparts E and G are not part of this information collection.

Description of Respondents: The respondent recordkeepers are manufacturers of exempt infant formula.

In the *Federal Register* of October 1, 2018 (83 FR 49393), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

We estimate the burden of the information collection as follows:

Table 1.--Estimated Annual Recordkeeping Burden[1]

21 CFR Section	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeper	Total Hours
First-Year Annual Burden					
Production and In-Process Control System--106.6(c)(5) and 106.100(e)(1), and (e)(3)	3	1	3	40	120
Controls to Prevent Adulteration due to Automatic (Mechanical or Electronic) Equipment--106.35(c) and 106.100(f)(5)	3	1	3	6,400	19,200
Total First Year Only Hourly Recordkeeping Burden					19,320
Recurring Annual Burden					
Controls to Prevent Adulteration Caused by Facilities--Testing for Radiological Contaminants--106.20(f)(3)	4	1	4	1.5	6
Controls to Prevent Adulteration Caused by Facilities--Recordkeeping of Testing for Radiological Contaminants--106.20(f)(4) and 106.100(f)(1)	4	1	4	0.08 (5 minutes)	0.32
Controls to Prevent Adulteration Caused by Facilities--Testing for Bacteriological Contaminants--106.20(f)(3)	3	52	156	0.08 (5 minutes)	12.48
Controls to Prevent Adulteration Caused by Facilities--Recordkeeping of Testing for Bacteriological Contaminants--106.20(f)(4) and 106.100(f)(1)	3	52	156	0.08 (5 minutes)	12.48
Controls to Prevent Adulteration by Equipment or Utensils--106.30(d)(1) and 106.100(f)(2)	3	52	156	0.21 (13 minutes)	32.76
Controls to Prevent Adulteration by Equipment or Utensils--106.30(e)(3)(iii) and 106.100(f)(3)	3	52	156	0.21 (13 minutes)	32.76
Controls to Prevent Adulteration by Equipment or Utensils--106.30(f)(2) and 106.100(f)(4)	3	52	156	0.19 (11 minutes)	29.64

Controls to Prevent Adulteration Due to Automatic (Mechanical or Electronic) Equipment--106.35(c) and 106.100(f)(5)	3	52	156	520	81,120
Controls to Prevent Adulteration Due to Automatic (Mechanical or Electronic) Equipment--106.35(c) and 106.100(f)(5)	3	2	6	640	3,840
Controls to Prevent Adulteration Caused by Ingredients, Containers, and Closures--106.40(g) and 106.100(f)(6)	3	52	156	0.17 (10 minutes)	26.52
Controls to Prevent Adulteration During Manufacturing--106.50 and 106.100(e)	3	52	156	0.23 (14 minutes)	35.88
Controls to Prevent Adulteration From Microorganisms--106.55(d), 106.100(e)(5)(ii), and 106.100(f)(7)	3	52	156	0.25 (15 minutes)	39
Controls to Prevent Adulteration During Packaging and Labeling of Infant Formula--106.60(c)	1	12	12	0.25 (15 minutes)	3
General Quality Control Testing--106.91(b)(1)-(3)	2	1	2	2	4
General Quality Control--106.91(b)(1), 106.91(d), and 106.100(e)(5)(i)	2	52	104	0.15 (9 minutes)	15.6
General Quality Control--106.91(b)(2) 106.91(d), and 106.100(e)(5)(i)	2	52	104	0.15 (9 minutes)	15.6
General Quality Control--106.91(b)(3) 106.91(d), and 106.100(e)(5)(i)	2	52	104	0.15 (9 minutes)	15.6
Audit Plans and Procedures--106.94; Ongoing Review and Updating of Audits	3	1	3	8	24
Audit Plans and Procedures--106.94; Regular Audits	3	52	156	4	624
Total Recurring Recordkeeping Burden					85,889.64
Total Recordkeeping Burden					105,209.64

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on a review of the information collection, we made a correction since the last OMB approval. While the one-time estimated recordkeeping burden remains as 19,320 hours, we increased the annual estimated recurring recordkeeping burden to 85,889.64 hours due to a

calculation error (a 79,561.58 hour increase) for a total recordkeeping burden of 105,209.64 hours.

Dated: February 27, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

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