III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm,* or *https://www.regulations.gov.*

Dated: September 25, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–21243 Filed 9–28–18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–3490]

Agency Information Collection Activities; Proposed Collection; 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 or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection provisions of the guidance entitled ''Guidance for Industry: Exempt Infant Formula Production: Current Good Manufacturing Practices (CGMPs), Quality Control Procedures, Conduct of Audits, and Records and Reports.''

DATES: Submit either electronic or written comments on the collection of information by November 30, 2018.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before November 30, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. midnight Eastern Time at the end of November 30, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2018–N–3490 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Exempt Infant Formula Production: Current Good Manufacturing Practices (CGMPs), Quality Control Procedures, Conduct of Audits, and Records.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or

provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

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), (b), and (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 *http://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 production 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.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR section	Number of recordkeepers	Number 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

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]—Continued

21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeper	Total hours
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), 106.91(b)(2) and 106.91(b)(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: September 25, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–21207 Filed 9–28–18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–3353]

Agency Information Collection Activities; Proposed Collection; Comment Request; Antimicrobial Animal Drug Distribution Reports and Recordkeeping

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection provisions of our reporting and recordkeeping requirements for antimicrobial animal drug sales and distribution.

DATES: Submit either electronic or written comments on the collection of information by November 30, 2018.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before November 30, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of November 30, 2018.