as well as the name, address, and phone number of its U.S. agent (§ 607.40(d)).

This information assists FDA in its inspections of facilities, among other uses, and its collection is essential to the overall regulatory scheme designed to ensure the safety of the Nation's blood supply.

Respondents to this collection of information are human blood and plasma donor centers, blood banks, certain transfusion services, other blood product manufacturers, and independent laboratories that engage in quality control and testing for registered blood product establishments.

FDA estimates the burden of this collection of information based upon information obtained from the database of FDA's Center for Biologics Evaluation and Research and FDA experience with the blood establishment registration and product listing requirements.

In the **Federal Register** of December 26, 2017 (82 FR 61013), FDA published a 60-day notice requesting public comment on the proposed collection of information. We received no comments.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section	Activity/form FDA 2830	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
607.20(a), 607.21, 607.22, 607.25, and 607.40.	Initial Registration.	115	1	115	1	115
607.21, 607.22, 607.25, 607.26, 607.31, and 607.40.	Annual Registration.	2,612	1	2,612	0.5 (30 minutes)	1,306
607.21, 607.25, 607.30(a), 607.31, and 607.40.	Product Listing Update.	200	1	200	0.25 (15 minutes)	50
607.22(b)	Waiver Requests	25		25	1	25
Total						1,496

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

The burden for this information collection has changed since the last OMB approval. Because of a slight increase in the number of initial registrations and product listing updates FDA has received during the past 3 years, we have increased our reporting burden estimate.

Dated: April 3, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–07145 Filed 4–6–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0545]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request

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 May 9, 2018.

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 0910–0256. Also include the FDA docket number found in brackets in the heading of this document.

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

Infant Formula Requirements—21 CFR parts 106 and 107

OMB Control Number 0910–0256—Extension

This information collection supports FDA regulations regarding infant formula requirements. Statutory requirements for infant formula under the Federal Food, Drug, and Cosmetic Act (FD&C Act) are intended to protect the health of infants and include a number of reporting and recordkeeping requirements. Among other things, section 412 of the FD&C Act (21 U.S.C. 350a) requires manufacturers of infant formula to establish and adhere to quality control procedures, notify us when a batch of infant formula that has left the manufacturers' control may be adulterated or misbranded, and keep records of distribution. We also regulate the labeling of infant formula under the authority of section 403 of the FD&C Act (21 U.S.C. 343). The purpose of the labeling requirements is to ensure that consumers have the information they need to prepare and use infant formula appropriately. The regulations for infant formula requirements are codified in 21 CFR parts 106 and 107.

To assist respondents with applicable reporting provisions found in the regulations, we have developed an electronic Form FDA 3978 that allows infant formula manufacturers to electronically submit reports and notifications in a standardized format. Form FDA 3978 prompts respondents to include information in a standardized format and helps respondents organize submissions to include only the information needed for our review. Draft screenshots of Form FDA 3978 and instructions are available at *https://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/InfantFormula/default.htm.* Form FDA 3978 was deployed in 2017 as a pilot by FDA and, while informal feedback regarding its use has been favorable, we continue to invite comment. If manufacturers prefer, however, FDA continues to accept paper submissions.

In the **Federal Register** of November 15, 2017, we published a notice inviting public comment on the proposed collection of information. No comments were received. We therefore retain our original burden estimate for the information collection, which is as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

FD&C act or 21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Reports; Section 412(d) of the FD&C Act	5	13	65	10	650
Notifications; § 106.120(b)	1	1	1	4	4
Reports for Exempt Infant Formula; § 107.50(b)(3) and (4)	3	2	6	4	24
Notifications for Exempt Infant Formula;§ 107.50(e)(2)	1	1	1	4	4
Requirements for Quality Factors Growth Monitoring Study Exemption; § 106.96(c).	4	9	36	20	720
Requirements for Quality Factors—PER Exemption; § 106.96(g)	1	34	34	12	408
New Infant Formula Registration; § 106.110	4	9	36	0.50 (30 minutes)	18
New Infant Formula Submission; § 106.120	4	9	36	10	360
Total					2,188

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

In compiling these estimates, we consulted our records of the number of infant formula submissions we received under the information collection. All infant formula submissions may be provided to us in electronic format. Our estimate of the time needed per response is based on our experience with similar programs and informal feedback we have received from industry.

We assume that we will receive 13 reports from 5 manufacturers under section 412(d) of the FD&C Act, for a total of 65 reports annually. We assume each report takes 10 hours to compile for a total of 650 hours annually. We also assume that we will receive one notification under § 106.120(b) and 4 hours is needed per response, for a total of 4 hours annually.

For exempt infant formula, we assume we will receive two reports from three manufacturers under § 107.50(b)(3) and (4), for a total of six reports annually. We assume each report takes 4 hours to compile for a total burden of 24 hours annually. We also assume we will receive one notification annually under § 107.50(e)(2) and that it takes 4 hours to prepare.

We assume that 4 firms will submit 36 exemptions under § 106.96(c) and that each exemption will take 20 hours to assemble for a total burden of 720 hours annually, as reflected in row 5 of table 1.

We assume that the infant formula industry annually submits 35 protein efficiency ratio (PER) submissions. For the submission of the PER exemption, we estimate that the infant formula industry submits 34 exemptions per year and that each exemption takes supporting staff 12 hours to prepare. Therefore, we calculate 34 exemptions × 12 hours per exemption = 408 hours to fulfill the requirements of § 106.96(g), as shown in row 6 of table 1.

We estimate that four firms each use one senior scientist or regulatory affairs professional who needs 30 minutes to gather and record the required information for an infant formula registration under § 106.110. We estimate that the industry annually registers 35 new infant formulas, or an average of 9 registrations per firm. Therefore, we calculate the annual burden as 36 registrations × 0.5 hour per registration = 17.5 (rounded to 18) hours, as shown in row 7 of table 1.

We estimate that four firms each use one senior scientist or regulatory affairs professional who needs 10 hours to gather and record information needed for infant formula submissions under § 106.120. This estimate includes the time needed to gather and record the information the manufacturer uses to request an exemption under § 106.91(b)(1)(ii), which provides that the manufacturer includes the scientific evidence that the manufacturer is relying on to demonstrate that the stability of the new infant formula will likely not differ from the stability of formula with similar composition, processing, and packaging for which there are extensive stability data. We estimate that 4 firms make submissions for 36 new infant formulas, or an average of 9 submissions per firm. Therefore, to comply with § 106.120, we calculate the annual burden as 36 submissions × 10 hours per submission = 360 hours, as shown in row 8 of table 1. Thus, the total annual reporting burden is 2,188 hours.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity; 21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Controls to prevent adulteration caused by facilities—testing for radiological contaminants; [3] § 106.20(f)(3)	21	1	21	1.5 (90 minutes)	32
Controls to prevent adulteration caused by facilities—recordkeeping of testing for radiological contaminants; [2] §§ 106.20(f)(4) and 106.100(f)(1)	21	1	21	0.08 (5 minutes)	2
Controls to prevent adulteration caused by facilities—testing for bacteriological contaminants § 106.20(f)(3)	5	52	260	0.08 (5 minutes)	21
Controls to prevent adulteration caused by facilities—recordkeeping of testing for bacteriological contaminants §§ 106.20(f)(4) and 106.100(f)(1)	5	52	260	0.08 (5 minutes)	21
Controls to prevent adulteration by equipment or utensils; §§ 106.30(d) and 106.100(f)(2)	5	52	260	0.22 (13 minutes)	57
Controls to prevent adulteration by equipment or utensils; §§ 106.30(e)(3)(iii) and 106.100(f)(3)	5	52	260	0.22 (13 minutes)	57

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]—Continued

Activity; 21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Controls to prevent adulteration by equipment or utensils; §§ 106.30(f) and 106.100(f)(4)	5	52	260	0.20 (12 minutes)	52
Controls to prevent adulteration due to automatic (mechanical or electronic) equipment; §§ 106.35(c) and 106.100(f)(5)	5	1	5	520	2,600
Controls to prevent adulteration due to automatic (mechanical or electronic) equipment §§ 106.35(c) and 106.100(f)(5)	5	2	10	640	6,400
Controls to prevent adulteration caused by ingredients, containers, and closures; §§ 106.40(d) and 106.100(f)(6)	5	52	260	0.17 (10 minutes)	44
Controls to prevent adulteration during manufacturing; §§ 106.50(a)(1) and 106.100(e)	5	52	260	0.23 (14 minutes)	60
Controls to prevent adulteration from microorganisms; §§ 106.55(d) and 106.100(e)(5)(ii) and (f)(7)	5	52	260	0.25 (15 minutes)	65
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), (2), and (3)	4	1	4	2	8
General quality control; §§ 106.91(b)(1) and(d), and 106.100(e)(5)(i)	4	52	208	0.15 (9 minutes)	31
General quality control; §§ 106.91(b)(2) and (d), and 106.100(e)(5)(i)	4	52	208	0.15 (9 minutes)	31
General quality control; §§ 106.91(b)(3) and (d), and 106.100(e)(5)(i)	4	52	208	0.15 (9 minutes)	31
Audit plans and procedures; ongoing review and updating of audits; § 106.94	5	1	5	8	40
Audit plans and procedures —regular audits; § 106.94	5	52	260	4	1,040
Requirements for quality factors for infant formulas—written study report; §§ 106.96(b) and (d), 106.100(p)(1) and (q)(1), and 106.121	1	1	1	16	16
Requirements for quality factors for infant formulas—anthropometric data; §§ 106.96(b)(2) and (d), and 106.100(p)(1)	112	6	672	0.50 (30 minutes)	336
Requirements for quality factors for infant formulas—formula intake §§ 106.96(b)(3) and (d), and 106.100(p)(1)	112	6	672	0.25 (15 minutes)	168
Requirements for quality factors for infant formulas—data plotting; §§ 106.96(b)(4) and (d), and 106.100(p)(1)	112	6	672	0.08 (5 minutes)	54
Requirements for quality factors for infant formulas—data comparison; §§ 106.96(b)(5) and (d), and 106.100(p)(1)	112	6	672	0.08 (5 minutes)	54
Requirements for quality factors—per data collection; § 106.96(f)	1	1	1	8	8
Requirements for quality factors—per written report; § 106.96(f)	1	1	1	1	1
Records; § 106.100	5	10	50	400	20,000
Records for Exempt Infant Formula; § 107.50(c)(3)	3	10	30	300	9,000
Total					40,232

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Where necessary, numbers have been rounded to the nearest whole number.
[3] This testing only occurs every 4 years.

We estimate that 21 infant formula plants will test at least every 4 years for radiological contaminants. In addition, we estimate that collecting water for all testing in § 106.20(f)(3) takes between 1 and 2 hours. We estimate that water collection takes an average of 1.5 hours and that water collection occurs separately for each type of testing. We estimate that performing the test will take 1.5 hours per test, every 4 years. Therefore, 1.5 hours per plant × 21 plants = 31.5 (rounded to 32) total hours, every 4 years, as seen in row 1 of table 2. Furthermore, §§ 106.20(f)(4) and 106.100(f)(1) require firms to make and retain records of the frequency and results of water testing. For the 21 plants that are estimated not to currently test for radiological contaminants, this burden is estimated to be 5 minutes per record every 4 years. Therefore, 0.08 hour per record × 21 plants = 1.68 (rounded to 2) hours, every 4 years for the maintenance of records of radiological testing, as seen on row 2 of table 2.

We estimate that five infant formula plants will test weekly for bacteriological contaminants. We estimate that performing the test will take 5 minutes per test once a week. Annually, this burden is 0.08 hours × 52 weeks = 4.16 hours per year, per plant, and 4.16 hours per plant × 5 plants = 20.8 (rounded to 21) total annual hours, as seen on row 3 of table 2. Furthermore, for the five plants that are estimated to not currently test weekly for bacteriological contaminants, this burden is estimated to be 5 minutes per record, every week. Therefore, 0.08 hour per record × 52 weeks = 4.16 hours per plant for the maintenance of records of bacteriological testing. Accordingly, 4.16 hours × 5 plants = 20.8 (rounded to 21) annual hours, as seen on row 4 of table 2.

Sections 106.30(d) and 106.100(f)(2) require that records of calibrating certain instruments be made and retained. We estimate that one senior validation engineer for each of the five plants will need to spend about 13 minutes per week to satisfy the ongoing calibration recordkeeping requirements. Therefore, 5 recordkeepers × 52 weeks = 260 records; 260 records × 0.22 hour per record = 57 hours as the annual burden, as presented in row 5 of table 2.

Sections 106.30(e)(3)(iii) and 106.100(f)(3)) require the recordkeeping of the temperatures of each cold storage compartment. We estimate that five plants will each require one senior validation engineer about 13 minutes per week of recordkeeping. Therefore, 5 recordkeepers × 52 weeks = 260 records; 260 records × 0.22 hours per record = 57 hours as the annual burden, as presented in row 6 of table 2.

Sections 106.30(f) and 106.100(f)(4) require the recordkeeping of ongoing sanitation efforts. We estimate that five plants will each require one senior validation engineer about 12 minutes

per week of recordkeeping. Therefore, 5 recordkeepers × 52 weeks = 260 records; 260 records × 0.20 hours per record = 52 hours as the annual burden, as presented in row 7 of table 2.

For §§ 106.35(c) and 106.100(f)(5), we estimate that one senior validation engineer per plant needs 10 hours per week of recordkeeping, with the annual burden for this provision being 520 hours per plant × 5 plants = 2,600 annual hours, as shown in row 8 of table 2. In addition, an infant formula manufacturer revalidates its systems when it makes changes to automatic equipment. We estimate that such changes occur twice a year, and that on each of the two occasions, a team of four senior validation engineers per plant needs to work full time for 4 weeks (4 weeks × 40 hours per week = 160 work hours per person) to provide revalidation of the plant's automated systems sufficient to comply with this section. The annual burden for four senior validation engineers each working 160 hours twice a year is 1,280 hours ((160 hours × 2 revalidations) × 4 engineers = 1,280 total work hours) per plant. Therefore, 640 hours × 5 plants × 2 times per year = 6,400 hours as the annual burden, as shown on row 9 of table 2.

Sections 106.40(d) and 106.100(f)(6) require written specifications for ingredients, containers, and closures. We estimate that one senior validation engineer per plant needs about 10 minutes a week to fulfill the recordkeeping requirements. Therefore, 5 recordkeepers × 52 weeks = 260 records and 260 records × 0.17 hour = 44 hours as the annual burden, as shown in row 10 of table 2.

We estimate that five plants will change a master manufacturing order and that one senior validation engineer for each of the five plants spends about 14 minutes per week on recordkeeping pertaining to the master manufacturing order, as required by §§ 106.50(a)(1) and 106.100(e). Thus, 5 recordkeepers × 52 weeks = 260 records; 260 records × 0.23 hour = 60 hours as the annual burden, as shown in row 11 of table 2.

Sections 106.55(d), 106.100(e)(5)(ii), and 106.100(f)(7)) require recordkeeping of the testing of infant formula for microorganisms. We estimate that five plants each need one senior validation engineer to spend 15 minutes per week on recordkeeping pertaining to microbiological testing. Thus, 5 recordkeepers × 52 weeks = 260 records; 260 records × 0.25 hour per record = 65 hours as the annual burden, as shown in row 12 of table 2.

Section 106.60 establishes requirements for the recordkeeping and labeling of mixed-lot packages of infant formula. Section 106.60(c) requires infant formula distributors to label infant formula packaging (such as packing cases) to facilitate product tracing and to keep specific records of the distribution of these mixed lot cases. We estimate that one worker needs 15 minutes, once a month (0.25 × 12 months) to accomplish this, for an annual burden of 3 hours, as shown in row 13 of table 2.

Sections 106.91(b)(1), (2), and (3) provide ongoing stability testing requirements. We estimate that the stability testing requirements has a burden of 2 hours per plant. Therefore, 2 hours × 4 plants = 8 hours as the annual burden to fulfill the testing requirements, as shown in row 14 of table 2.

Sections 106.91(d) and 106.100(e)(5)(i) provide for recordkeeping of tests required under § 106.91(b)(1), (2), and (3). We estimate that one senior validation engineer per plant will spend about 9 minutes per week of recordkeeping to be in compliance. Thus, 4 recordkeepers × 52 weeks = 208 records; 208 records × 0.15 hour per record = 31.2 (rounded to 31) hours for the annual burden, as shown in rows 15, 16, and 17 of table 2.

We estimate that the ongoing review and updating of audit plans requires a senior validation engineer 8 hours per year, per plant. Therefore, 8 hours × 5 plants = 40 hours for the annual burden, as shown in row 18 of table 2.

We estimate that a manufacturer chooses to audit once per week. We estimate each weekly audit requires a senior validation engineer 4 hours, or 52 weeks × 4 hours = 208 hours per plant. Therefore, burden for updating audit plans is calculated as 208 hours × 5 plants = 1,040 hours for the annual burden, as shown in row 19 of table 2.

We estimate that, as a result of the regulations, the industry as a whole performs one additional growth study per year, in accordance with § 106.96. The regulations require that several pieces of data be collected and maintained for each infant in the growth study. We estimate that the data collection associated with the growth study is assembled into a written report and kept as a record in compliance with §§ 106.96(d) and 106.100(p)(1). Thus, we estimate that one additional growth study report is generated, and that this report requires one senior scientist to work 16 hours to compile the data into a study report. Therefore, one growth study report × 16 hours = 16 hours for the annual burden for compliance with §§ 106.96(b) and (d), 106.100(p)(1) and (q)(1), and 106.121 as shown in row 20 of table 2.

A study conducted according to the requirements of § 106.96(b)(2) must include the collection of anthropometric measurements of physical growth and information on formula intake, and §§ 106.96(d) and 106.100(p)(1) require that the anthropometric measurements be made six times during the growth study. We estimate that in a growth study of 112 infants, 2 nurses or other health professionals with similar experience need 15 minutes per infant at each of the required 6 times to collect and record the required anthropometric measurements. Therefore, 2 nurses × 0.25 hours = 0.50 hour per infant, per visit, and 0.50 hour × 6 visits = 3 hours per infant. For 112 infants in the study, 3 hours × 112 infants = 336 hours for the annual burden, as shown in row 21 of table 2. In addition, we estimate that one nurse needs 15 minutes per infant to collect and record the formula intake information. That is, 0.25 hour × 6 visits = 1.5 hour per infant, and 1.5 hour per infant × 112 infants = 168 hours for the annual burden, as shown in row 22 of table 2.

Section 106.96(b)(4) requires plotting each infant's anthropometric measurements on the Centers for Disease Control and Prevention-recommended World Health Organization Child Growth Standards. We estimate that it takes 5 minutes per infant to record the anthropometric data on the growth chart at each study visit. Therefore, 112 infants × 6 data plots = 672 data plots, and 672 data plots × 0.08 hour per comparison = 53.75 hours (rounded to 54) for the annual burden, as shown in row 23 of table 2.

Section 106.96(b)(5) requires that data on formula intake by the test group be compared to the intake of a concurrent control group. We estimate that one nurse or other health care professional with similar experience needs 5 minutes per infant for each of the six times anthropometric data are collected. Therefore, 6 comparisons of data × 112 infants = 672 data comparisons and 672 data comparisons × 0.08 hour per comparison = 53.75 hours (rounded to 54) for the annual burden, as shown in row 24 of table 2.

Section 106.96(f) provides that a manufacturer meets the quality factor of sufficient biological quality of the protein by establishing the biological quality of the protein in the infant formula when fed as the sole source of nutrition using an appropriate modification of the PER rat bioassay. Under § 106.96(g)(1), a manufacturer of infant formula may be exempt from this requirement if the manufacturer

requests an exemption and provides assurances, as required under § 106.121, that changes made by the manufacturer to an existing infant formula are limited to changing the type of packaging. A manufacturer may also be exempt from this requirement under § 106.100(g)(2), if the manufacturer requests an exemption and provides assurances, as required under § 106.121, that demonstrate to FDA's satisfaction that the change to an existing formula does not affect the bioavailability of the protein. Finally, a manufacturer of infant formula may be exempt from this requirement under § 106.96(g)(3) if the manufacturer requests an exemption and provides assurances, as required under § 106.121(i), that demonstrate that an alternative method to the PER that is based on sound scientific principles is available to show that the formula supports the quality factor for the biological quality of the protein. We estimate that the infant formula industry submits a total of 35 PER submissions: 34 exemption requests and the results of 1 PER study.

A PER study conducted according to the Association of Analytical Communities Official Method 960.48 is 28 days in duration. We estimate that there will be 10 rats in the control and test groups (20 rats total) and that food consumption and body weight will be measured at day 0 and at 7-day intervals during the 28-day study period (a total of 5 records per rat). We further estimate that measuring and recording food consumption and body weight will take 5 minutes per rat. Therefore, 20 rats × 5 records = 100 records; 100 records × 0.08 hour minutes per record = 8 hours to fulfill the requirements of § 106.96(f). Further, we estimate that a report based on the PER study will be generated and that this study report will take a senior scientist 1 hour to generate. Therefore, a total of 9 hours will be required to fulfill the requirements for § 106.96(f): 8 hours for the PER study and data collection, and 1 hour for the development of a report based on the PER study, as shown in rows 25 and 26 of table 2.

We estimate that five firms will expend approximately 20,000 hours per year to fully satisfy the recordkeeping requirements in § 106.100 and that three firms will expend approximately 9,000 hours per year to fully satisfy the recordkeeping requirements in § 107.50(c)(3). Thus, the total recordkeeping burden is 40,232 hours.

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

21 CFR section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Nutrient labeling; 21 CFR 107.10(a) and 107.20	5	13	65	8	520

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

We estimate compliance with our labeling requirements in §§ 107.10(a) and 107.20 requires 520 hours annually by five manufacturers.

Dated: April 3, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–07147 Filed 4–6–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2014–N–0075; FDA–2011–N–0015; FDA–2011–N–0076; FDA–2017–N–0932; FDA–2016–N–4487; FDA–2014–N–0345; FDA–2013–N–0523; FDA–2017–N–2428; FDA–2008–N–0312; and FDA–2014–N–1072]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approvals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of information collections that have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The following is a list of FDA information collections recently approved by OMB under section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507). The OMB control number and expiration date of OMB approval for each information collection are shown in table 1. Copies of the supporting statements for the information collections are available on the internet at *https://www.reginfo.gov/public/do/PRAMain.* An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

TABLE 1—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB

Title of collection	OMB Control No.	Date approval expires
Good Laboratory Practice Regulations for Nonclinical Studies	0910–0119	1/31/2021
Orphan Drug Designation Request Form and The Common European Medicines Agency/Food and Drug Administration Form for Orphan Medicinal Product Designation	0910–0167	1/31/2021
Electronic Records: Electronic Signatures	0910–0303	1/31/2021
Experimental Study on Warning Statements for Cigarette Graphic Health Warnings	0910–0848	1/31/2021