FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The applications will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than December 11, 2017.

A. Federal Reserve Bank of San Francisco (Gerald C. Tsai, Director, Applications and Enforcement) 101 Market Street, San Francisco, California 94105–1579:

1. *CBC Bancorp;* to become a bank holding company by acquiring 98.3 percent of the voting shares of NCAL Bancorp, and thereby indirectly acquire Commercial Bank of California, all of Irvine, California.

Board of Governors of the Federal Reserve System, November 8, 2017.

Yao-Chin Chao,

Assistant Secretary of the Board.

[FR Doc. 2017–24653 Filed 11–14–17; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0545]

Agency Information Collection Activities; Proposed Collection; Comment Request; Infant Formula Requirements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA 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 invites comments on the information collection provisions of our infant formula regulations, including infant formula labeling, quality control procedures, notification requirements, and recordkeeping. The notice also invites comment on a pilot electronic form that allows manufacturers of infant formula to submit reports and notifications in a standardized format.

DATES: Submit either electronic or written comments on the collection of information by January 16, 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 January 16, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of January 16, 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–2013–N–0545 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Infant Formula Requirements.'' 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: 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: 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, we invite 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.

Infant Formula Requirements—21 CFR parts 106 and 107

OMB Control Number 0910–0256—Extension

Statutory requirements for infant formula under the Federal Food, Drug, and Cosmetic Act (the 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 have issued regulations to implement the FD&C Act's requirements for infant formula in parts 106 and 107 (21 CFR parts 106 and 107). We also regulate the labeling of infant formula under the authority of section 403 of the FD&C Act (21 U.S.C. 343). Under our labeling regulations for infant formula in part 107, the label of an infant formula must include nutrient information and directions for use. The purpose of these labeling requirements is to ensure that consumers have the information they need to prepare and use infant formula appropriately.

We have developed an electronic form (Form FDA 3978) that infant formula manufacturers will be able to use to electronically submit reports and notifications in a standardized format to FDA. Manufacturers that prefer to submit paper submissions in a format of their own choosing will still have the option to do so, however. Form FDA 3978 prompts a respondent to include reports and notifications in a standard electronic format and helps the respondent organize their submission to include only the information needed for our review. Draft screenshots of Form FDA 3978 and instructions are available for comment at *http://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/InfantFormula/default.htm.*

Description of Respondents: Respondents to this information collection are manufacturers of infant formula.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Row No.	FD&C Act or 21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
1	Reports; Section 412(d) of the FD&C Act	5	13	65	10	650
2	Notifications; § 106.120(b)	1	1	1	4	4
3	Reports for Exempt Infant Formula; § 107.50(b)(3) and (4).	3	2	6	4	24
4	Notifications for Exempt Infant Formula;§ 107.50(e)(2).	1	1	1	4	4
5	Requirements for Quality Factors Growth Monitoring Study Exemption; § 106.96(c).	4	9	36	20	720
6	Requirements for Quality Factors—PER Exemption; § 106.96(g).	1	34	34	12	408
7	New Infant Formula Registration; § 106.110	4	9	36	0.50 (30 minutes).	18
8	New Infant Formula Submission; § 106.120	4	9	36	10	360
	Total					2,188

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

In compiling these estimates, we consulted our records of the number of infant formula submissions received in the past. All infant formula submissions may be provided to us in electronic format. The hours per response reporting estimates are based on our experience with similar programs and information received from industry.

We estimate that we will receive 13 reports from 5 manufacturers annually under section 412(d) of the FD&C Act, for a total annual response of 65 reports. Each report is estimated to take 10 hours per response for a total of 650 hours. We also estimate that we receive one notification under § 106.120(b). The notification is expected to take 4 hours per response, for a total of 4 hours.

For exempt infant formula, we estimate that we receive two reports from three manufacturers annually under § 107.50(b)(3) and (4), for a total annual response of six reports. Each report is estimated to take 4 hours per response for a total of 24 hours. We also estimate that we receive one notification annually under § 107.50(e)(2) and that the notification takes 4 hours to prepare.

We estimate that 4 firms submit 36 exemptions annually and that each exemption will take 20 hours to assemble. Therefore, we calculate 36 exemptions × 20 hours = 720 hours as the estimated burden for § 106.96(c), as presented in row 5 of table 1.

We estimate 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 pursuant to § 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 pursuant to § 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] [2]

Row No.	Activity; 21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
1	Controls to prevent adulteration caused by facilities—testing for radiological contaminants [3]; § 106.20(f)(3).	21	1	21	1.5 (90 minutes)	32
2	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
3	Controls to prevent adulteration caused by facilities—testing for bacteriological contaminants § 106.20(f)(3).	5	52	260	0.08 (5 minutes)	21
4	Controls to prevent adulteration caused by facilities—recordkeeping of testing for bacteriological contaminants §§ 106.20(f)(4) and 106.100(f).	5	52	260	0.08 (5 minutes)	21
5	Controls to prevent adulteration by equipment or utensils; §§ 106.30(d) and 106.100(f)(2).	5	52	260	0.22 (13 minutes)	57
6	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
7	Controls to prevent adulteration by equipment or utensils; §§ 106.30(f) and 106.100(f)(4).	5	52	260	0.20 (12 minutes)	52

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

Row No.	Activity; 21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
8	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
9	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
10	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
11	Controls to prevent adulteration during manufacturing; §§ 106.50(a)(1) and 106.100(e).	5	52	260	0.23 (14 minutes)	60
12	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
13	Controls to prevent adulteration during packaging and labeling of infant formula; § 106.60(c).	1	12	12	0.25 (15 minutes)	3
14	General quality control—testing; § 106.91(b)(1), (2), and (3).	4	1	4	2	8
15	General quality control; §§ 106.91(b)(1) and(d), and 106.100(e)(5)(i).	4	52	208	0.15 (9 minutes)	31
16	General quality control; §§ 106.91(b)(2) and (d), and 106.100(e)(5)(i).	4	52	208	0.15 (9 minutes)	31
17	General quality control; §§ 106.91(b)(3) and (d), and 106.100(e)(5)(i).	4	52	208	0.15 (9 minutes)	31
18	Audit plans and procedures; ongoing review and updating of audits; § 106.94.	5	1	5	8	40
19	Audit plans and procedures —regular audits; § 106.94.	5	52	260	4	1,040
20	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
21	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
22	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
23	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
24	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

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

Row No.	Activity; 21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
25	Requirements for quality factors—per data collection; § 106.96(f).	1	1	1	8	8
26	Requirements for quality factors—per written report; § 106.96(f).	1	1	1	1	1
27	Records; § 106.100	5	10	50	400	20,000
28	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 diverters 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-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: November 8, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–24688 Filed 11–14–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meetings Announcement for the Physician-Focused Payment Model Technical Advisory Committee Required by the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA)

ACTION: Notice of public meetings.

SUMMARY: This notice announces the next meeting of the Physician-Focused Payment Model Technical Advisory Committee (hereafter referred to as ''the Committee'') which will be held in Washington, DC. This meeting will include voting and deliberations on proposals for physician-focused payment models (PFPMs) submitted by members of the public. All meetings are open to the public.

DATES: The PTAC meeting will occur on the following dates:

- Monday–Wednesday, December 18–20, 2017, from 9:00 a.m. to 5:00 p.m. ET.

Please note that times are subject to change. If the times change, registrants will be notified directly via email.

ADDRESSES: The December 18–20, 2017 meeting will be held at the Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201.

FOR FURTHER INFORMATION CONTACT: Ann Page, Designated Federal Official, at the Office of Health Policy, Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services, 200 Independence Ave. SW., Washington, DC 20201, (202) 690–6870.

SUPPLEMENTARY INFORMATION:

I. Purpose

The Physician-Focused Payment Model Technical Advisory Committee (''the Committee'') is required by the Medicare Access and CHIP Reauthorization Act of 2015, 42 U.S.C. 1395ee. This Committee is also governed by provisions of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), which sets forth standards for the formation and use of federal advisory committees. In accordance with its statutory mandate, the Committee is to review physician-focused payment model proposals and prepare recommendations regarding whether such models meet criteria that were established through rulemaking by the Secretary of Health and Human Services (the Secretary). The Committee is composed of 11 members appointed by the Comptroller General.

II. Agenda

At the December 18–20, 2017 meeting, the Committee will hear presentations on PFPMs that are ready for Committee deliberation. The presentations will be followed by public comment and Committee deliberation. If the Committee completes deliberations, voting will occur on recommendations to the Secretary of Health and Human Services. There will be time allocated for public comment on agenda items. Documents will be posted on the Committee Web site and distributed on the Committee listserv prior to the public meeting. The agenda is subject to change. If the agenda does change, we will inform registrants and update our Web site to reflect any changes.

III. Meeting Attendance

The meeting is open to the public. The public may also attend via conference call or view the meeting via livestream at *www.hhs.gov/live.* The conference call dial-in information will be sent to registrants prior to the meeting.

Meeting Registration

The public may attend the meetings in-person or participate by phone via audio teleconference. Space is limited and registration is preferred in order to attend in-person or by phone. Registration may be completed online at *www.regonline.com/PTACMeetingsRegistration.*

The following information is submitted when registering:

Name:

Company/organization name:

Postal address:

Email address:

Persons wishing to attend this meeting must register by following the instructions in the ''Meeting Registration'' section of this notice. A confirmation email will be sent to registrants shortly after completing the registration process.

IV. Special Accommodations

If sign language interpretation or other reasonable accommodation for a disability is needed, please contact Angela Tejeda, no later than December 4, 2017. Please submit your requests by email to *Angela.Tejeda@hhs.gov* or by calling 202–401–8297.

V. Copies of the PTAC Charter and Meeting Material

The Secretary's Charter for the Physician-Focused Payment Model Technical Advisory Committee is available on the ASPE Web site at *https://aspe.hhs.gov/charter-physician-focused-payment-model-technical-advisory-committee.*

Additional material for this meeting can be found on the PTAC Web site. For updates and announcements, please use the link to subscribe to the PTAC email listserv.

Dated: September 12, 2017.

John R. Graham,

Acting Assistant Secretary for Planning and Evaluation.

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