III. Participating in the Public Workshop

Registration: Persons interested in attending this public workshop must register online by May 26, 2021, at *https://www.eventbrite.com/e/model-informed-drug-development-approaches-for-immunogenicity-assessments-tickets-138618787525.* Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone. Registration is free and based on space availability, with priority given to early registrants.

If you need special accommodations due to a disability, please contact Loni Warren Henderson or Sherri Revell (see **FOR FURTHER INFORMATION CONTACT**) no later than May 26, 2021. Please note, Computer Aided Realtime Translation/captioning will be available.

Streaming Webcast of the Public Workshop: This public workshop will be streamed via webcast only.

If you have never attended a Connect Pro event before, test your connection at *https://collaboration.fda.gov/common/help/en/support/meeting_test.htm.* To get a quick overview of the Connect Pro program, visit *https://www.adobe.com/go/connectpro_overview.* FDA has verified the website addresses in this document as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

Transcripts: Please be advised that as soon as a transcript of the public workshop is available, it will be accessible at *https://www.regulations.gov.* It may be viewed at the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500. A link to the transcript will also be available on the internet at *https://www.fda.gov/vaccines-blood-biologics/news-events-biologics/workshops-meetings-conferences-biologics.*

Dated: April 20, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–08487 Filed 4–22–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0190]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) 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: Submit written comments (including recommendations) on the collection of information by May 24, 2021.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 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

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 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. Failure to comply with any of the applicable labeling regulations will render an infant formula misbranded under section 403 of the FD&C Act. The purpose of these labeling requirements is to ensure that consumers have the information they need to prepare and use infant formula appropriately.

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 subsections 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 subsections 412(a), (b), and (c) of the FD&C Act.

In support of exempt infant formulas, 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, and is available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-exempt-infant-formula-production.*

We have also developed electronic Form FDA 3978 (Infant Formula Tracking System (IFTRACK)) so that infant formula manufacturers may electronically submit reports and notifications in a standardized format to FDA. However, manufacturers that prefer to submit paper submissions in a

format of their own choosing will still have the option to do so. 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. Screenshots of Form FDA 3978 and instructions are available at *https://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/InfantFormula/default.htm.*

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

In the **Federal Register** of December 2, 2020 (85 FR 77469), we published a 60-day notice requesting public comment on the proposed collection of information. Two comments were received providing general comment regarding requirements for infant formula labeling; however, neither comment requested revision to the burden estimates.

We estimate the burden of this collection of information 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—Protein Efficiency Ratio 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.

Based on a review of the information collection, we have adjusted our burden estimate to correct a nominal calculation error. This reflects a decrease of 62 annual responses and a corresponding decrease of 308 annual hours.

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.

The total estimated annual reporting burden is 2,188 hours, as shown in table 1.

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

FD&C Act or 21 CFR Part	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Part 106—subpart B: CGMP Requirements	5	429.8	2,149	4.4	9,414
Part 106—subparts C through G: Quality control; audits; quality factors; records and reports	5	726.8	3,634	6	21,818
Part 107—subpart C; Exempt infant formulas	3	10	30	300	9,000
Exempt infant formula production; GMP; audits, recordkeeping, and reports	3	634	1,902	45	85,590
Total					125,822

[1] There are no capital costs or operating and maintenance costs associated with the information.
[2] Numbers have been rounded.

The total estimated annual recordkeeping burden is 125,822 hours, as shown in table 2.

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

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

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

We estimate compliance with our infant formula labeling requirements in 21 CFR 107.10(a) and 107.20 requires 520 hours annually.

Dated: April 15, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–08470 Filed 4–22–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request Information Collection Request Title: Health Center Program: COVID–19 Data Collection Tools, OMB No. 0906–0062—Revision

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than June 22, 2021.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14N136B, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at (301) 443–1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference.

Information Collection Request Title: Health Center Program: COVID–19 Data Collection Tools, OMB No. 0906–0062—Revision.

Abstract: This information collection request was previously approved by OMB on June 11, 2020, as an emergency clearance (OMB No.: 0906–0062). HRSA is currently undertaking the standard Paperwork Reduction Act process for normal OMB approval.

During the COVID–19 public health emergency, HRSA-supported health centers and Federally Qualified Health Center Look-Alikes (look-alikes) have played a key role in providing testing and care for those affected by the virus. HRSA awarded billions of dollars in new funding to support health center awardees and look-alikes in the detection, prevention, diagnosis, and treatment of COVID–19. This funding has enabled health centers to maintain or increase their staffing levels, conduct training, provide COVID–19 treatment, and administer millions of tests for both existing and new patients. In addition, HRSA, in collaboration with Centers for Disease Control and Prevention, launched the Health Center COVID–19 Vaccine program as part of a White House initiative focused on health equity. This occurred in February 2021 to directly allocate COVID–19 vaccines to HRSA-supported health centers.

This ICR to support the implementation of COVID–19 relief funding and response activities includes forms previously submitted in the emergency information collection request clearance: (1) Health Center COVID–19 Data Collection Survey Tool, (2) Addendum to COVID–19 Data Collection Survey Tool, and (3) the Health Center COVID–19 Vaccine Program Readiness Assessment Tool. This revised information collection request includes two newly added forms: (1) Primary Care Association (PCA) COVID–19 Data Collection Survey Tool [1] and (2) the Health Center COVID–19 Vaccine Program Conditions of Participation Agreement.

Need and Proposed Use of the Information: HRSA uses the data collected to optimize COVID–19 testing and vaccination; track health center capacity and the impact of COVID–19 on operations, patients, and staff; and better understand training and technical assistance, funding, and other health center resource needs. The data allow HRSA to assess health center capacity prior to program enrollment, supporting successful vaccine allocation strategies while providing HRSA with information on the effectiveness of vaccine distribution through this program. In addition, the data inform HRSA in resource allocation and technical assistance to health centers.

The readiness assessment supports HRSA's analysis of health center ability to successfully participate in the Health Center COVID–19 Vaccine Program. These data are critical to determine health center capacity to implement the vaccination program as well as comply with program requirements. These data are used to assess program readiness including:

- Ability to safely store the vaccine
- Availability of trained and credentialed staff and other staff capacity
- Reporting capacity
- Sufficient Personal Protective Equipment
- Plan for vaccine transport

The health center weekly survey and addendum support HRSA's ability to monitor progress towards the development and delivery of COVID–19 prevention, preparedness, and/or response activities and ensure appropriate vaccine administration as well as better understand training and technical assistance, funding, and other health center resource needs.

The Conditions of Participation Agreement governs all COVID–19 vaccination activities at all health center sites that receive COVID–19 vaccine through the HRSA Health Center

[1] The bi-weekly COVID–19 PCA Survey Tool (comprised of six questions) is currently approved under the HHS Secretary's Public Health Emergency Authority to waive the requirements of the Paperwork Reduction Act during the Public Health Emergency for reporting on a voluntary basis.