II. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products.* This guidance document is also available at *https://www.regulations.gov* or *https://www.fda.gov/regulatory-information/search-fda-guidance-documents.* Persons unable to download an electronic copy of ''Transition Plan for Medical Devices Issued Emergency Use Authorizations (EUAs) Related to Coronavirus Disease 2019 (COVID–19)'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number GUI00020042 and complete title to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

This guidance refers to previously approved FDA collections of information. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA). The collections of information in the following FDA regulations and guidance have been approved by OMB as listed in the table below.

This guidance also contains new collections of information not approved under a current collection. These new collections of information have been granted a PHE waiver from the PRA by HHS on March 19, 2020, under section 319(f) of the PHS Act. Information concerning the PHE PRA waiver can be found on the HHS website at *https://aspe.hhs.gov/public-health-emergency-declaration-pra-waivers.*

CFR cite referenced in this guidance	Another guidance referenced in this guidance	OMB control No(s).	New collection covered by PHE PRA waiver
	''Emergency Use Authorization of Medical Products and Related Authorities; Guidance for Industry and Other Stakeholders''.	0910–0595	
	''Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program Guidance for Industry and Food and Drug Administration Staff''.	0910–0756	
	''Administrative Procedures for CLIA Categorization'' and ''Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices—Guidance for Industry and FDA Staff''.	0910–0607	
800, 801, and 809		0910–0485	
803		0910–0437	
806		0910–0359	
807, subparts A through D		0910–0625	
807, subpart E		0910–0120	
812		0910–0078	
814, subparts A through E		0910–0231	
814, subpart H		0910–0332	
820		0910–0073	
830 and 801.20		0910–0720	
860, subpart D		0910–0844	
			Notification of Intent.
			Transition Implementation Plan.
			Labeling Mitigation for Certain Reusable Devices.

Dated: March 22, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–06292 Filed 3–24–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–D–0814]

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 (PRA).

DATES: Submit written comments (including recommendations) on the collection of information by April 26, 2023.

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 Under the Federal Food, Drug, and Cosmetic Act—21 CFR Parts 106 and 107

OMB Control Number 0910–0256—Revision

This information collection supports FDA regulations, and associated Agency forms and guidance, pertaining to infant formula requirements. Statutory provisions for infant formula under the Federal Food, Drug, and Cosmetic Act (FD&C Act) were enacted to protect the health of infants and include specific current good manufacturing practice (CGMP), labeling (disclosure), and a number of reporting and recordkeeping requirements. Section 412 of the FD&C Act (21 U.S.C. 350a) requires manufacturers of infant formula to establish and document the adherence to quality control procedures, notify FDA when a batch of infant formula that has left the manufacturers' control may be adulterated or misbranded, and keep records of infant formula distribution. Notification requirements are also included in the regulations regarding the quantitative formulation of the infant formula; a description of any reformulation or change in processing; assurances that the formula will not be marketed until regulatory requirements are met as demonstrated by specific testing; and assurances that manufacturing processes comply with the regulations. The regulations are found in 21 CFR part 106: Infant Formula Requirements Pertaining to Current Good Manufacturing Practice, Quality Control Procedures, Quality Factors, Records and Reports, and Notifications; and 21 CFR part 107: Infant Formula.

We have revised the information collection as part of the Federal Government's response to address ongoing disruptions in the infant formula supply. We communicated our initial efforts to address the infant formula shortage in the May 2022 guidance entitled ''Infant Formula Enforcement Discretion Policy: Guidance for Industry'' (May 2022 guidance; available at: *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-infant-formula-enforcement-discretion-policy*). To clarify whether products currently subject to enforcement discretion would be able to remain on the market, we issued the September 2022 guidance entitled ''Infant Formula Transition Plan for Exercise of Enforcement Discretion: Guidance for Industry'' (September 2022 guidance; available at: *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-infant-formula-transition-plan-exercise-enforcement-discretion*). The September 2022 guidance sets out a pathway for manufacturers of infant formula that began marketing infant formula products in the United States after receiving a letter of enforcement discretion based on information provided in response to the May 2022 guidance to seek to continue marketing such products under enforcement discretion while they work to bring their infant formula products fully into compliance with applicable requirements.

In the **Federal Register** of October 6, 2022 (87 FR 60689), FDA announced that we had requested, and OMB had approved, emergency processing of the proposed collection of information under section 3507(j) of the PRA (44 U.S.C. 3507(j) and 5 CFR 1320.13) and invited public comment, instructing comments be submitted to OMB. No comments have been received. On our own initiative, however, we are also revising the collection to account for voluntary notifications pertaining to product samples found to be positive for *Cronobacter* spp. or *Salmonella,* even if the affected lot(s) have not been distributed. FDA has requested this information to help prevent future *Cronobacter* spp. illnesses associated with powdered infant formula. As part of a constituent update, available at *https://www.fda.gov/food/cfsan-constituent-updates/fda-calls-enhanced-safety-measures-letter-powdered-infant-formula-industry,* we issued a letter on March 8, 2023, to share current information to assist industry in improving the microbiological safety of powdered infant formula. As communicated in the letter, we shared the information with the expectation that infant formula manufacturers, packers, distributors, exporters, importers, and retailers will act to mitigate potential food safety risks in powdered infant formula in accordance with FDA regulations while further striving to improve operations, especially given the critical nature of these products.

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

TABLE 1—ESTIMATED ONE-TIME ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Submit information in accordance with timing and content schedule discussed in guidance document for both exempt and non-exempt infant formulas.	115	1	115	24	2,760
Letter of Intent	11	1	11	5	55
Plan to Meet Applicable Infant Formula Requirements.	11	1	11	90	990
Voluntary Submission of sample results as described in constituent update of March 8, 2023.	20	1	20	0.25 (15 minutes)	5
Total					3,810

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

Our estimate is based on submissions received in response to the May 2022 guidance, for which we account for 115 respondents, each of whom submitted 1 request. We assume it requires an average of 24 hours to prepare each submission, and therefore calculate a total of 2,760 burden hours (115 requests × 24 hours). Although originally we assumed 15 respondents would initiate requesting enforcement discretion, out of those 115 respondents,

we have issued letters of enforcement discretion to 12 of them. We received letters from 11 of these respondents indicating their intent to bring their products fully into compliance with applicable regulatory requirements and requesting that we continue to exercise enforcement discretion in the interim, and have therefore adjusted the number of respondents associated with the corresponding activities accordingly. We assume each request requires an average of 5 hours to prepare, for a total of 55 burden hours (11 letters × 5 hours). We estimate these same respondents will then submit a compliance plan and assume each plan will require an average of 90 hours to prepare, for a total of 990 burden hours (11 plans × 90 hours).

We estimate the burden associated with the voluntary notification of positive sampling results as discussed in our March 8, 2023, letter to be 20 responses and 5 hours annually, assuming 15 minutes is necessary for the completion of this activity. We also assume respondents will utilize established notification methods found on our website or by contacting the FDA district office in which the positive sampling results have occurred.

Dated: March 22, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–06249 Filed 3–24–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–D–0110]

Clinical Trial Considerations To Support Accelerated Approval of Oncology Therapeutics; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Clinical Trial Considerations to Support Accelerated Approval of Oncology Therapeutics.'' The purpose of this guidance is to provide recommendations to sponsors of anti-cancer drugs or biological products on considerations for designing trials intended to support accelerated approval. The accelerated approval pathway is commonly used for approval of oncology drugs due to the serious and life-threatening nature of cancer. Although single-arm trials have been commonly used to support accelerated approval, a randomized controlled trial is the preferred approach as it provides a more robust efficacy and safety assessment and allows for direct comparisons to an available therapy. This guidance describes considerations for designing, conducting, and analyzing data for trials intended to support accelerated approvals of oncology therapeutics.

DATES: Submit either electronic or written comments on the draft guidance by May 26, 2023 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

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–2023–D–0110 for ''Clinical Trial Considerations to Support Accelerated Approval of Oncology Therapeutics.'' Received comments 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, 240–402–7500.

- 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.govinfo.gov/content/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, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food