OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number: ____, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, please access the CMS PRA website by copying and pasting the following web address into your web browser: *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.*

FOR FURTHER INFORMATION CONTACT: William N. Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS–1561/1561A Health Insurance Benefit Agreement

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. The term ''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 requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collection

1. *Type of Information Collection Request:* Reinstatement without change of a previously approved collection; *Title of Information Collection:* Health Insurance Benefit Agreement; *Use:* The CMS–1561 form applies to specific types of health care providers and opioid treatment programs and the CMS–1561A form applies to rural health clinics (RHCs). The CMS–1561 and CMS–1561A forms are health insurance benefits agreements that are essential for the Centers for Medicare and Medicaid Services (CMS) to ensure that applicants to the Medicare program have made a binding commitment to comply with all applicable Federal requirements. The CMS–1561/1561A forms are essential in that they allow CMS to ensure that applicants are in compliance with the requirements. Applicants will be required to sign the completed form and provide operational information to CMS to assure that they continue to meet the requirements after approval. The collection is made only once, when the provider or RHC submits their application for participation in Medicare by signing the completed CMS–1561 or CMS–1561A form (as applicable). *Form Number:* CMS–1561/1561A (OMB control number: 0938–0832); *Frequency:* Once only; *Affected Public:* Private sector—(Business or other for-profits and Not-for-profit institutions); *Number of Respondents:* 2,050; Total *Annual Responses:* 2,050; *Total Annual Hours:* 2,050. (For policy questions regarding this collection contact Caroline Gallaher at 410–786–8705).

Dated: September 25, 2023

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2023–21334 Filed 9–28–23; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3383–N2]

Clinical Laboratory Improvement Amendments of 1988 Exemption of Laboratories Licensed by the State of Washington; Exemption Period Extension

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Notice; exemption period extension.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) announce the extension of the Clinical Laboratory Improvement Amendments of 1988 (CLIA) exemption period for the State of Washington. The exemption period is extended for 6 months, that is until April 2, 2024.

DATES: The exemption granted by this notice is effective from October 2, 2023 to April 2, 2024.

FOR FURTHER INFORMATION CONTACT: Mary Hasan, (410) 786–6480.

SUPPLEMENTARY INFORMATION: In the ''Medicare, Medicaid, and CLIA Programs; Clinical Laboratory Improvement Amendments of 1988 Exemption of Laboratories Licensed by the State of Washington'' notice that appeared in the September 30, 2019 **Federal Register** (84 FR 51591), we announced that laboratories located in and licensed by the State of Washington that possess a valid license under the Medical Test Site law, Chapter 70.42 of the Revised Code of Washington, are exempt from the requirements of the Clinical Laboratory Improvement Amendments of 1988 (CLIA) for a period of 4 years. This period expires on October 2, 2023. Pending re-approval of Washington State's CLIA exemption period, we are extending Washington State's current CLIA exemption period for 6 months, that is until April 2, 2024.

The Administrator of CMS, Chiquita Brooks-LaSure, having reviewed and approved this document, authorizes Chyana Woodard, who is the **Federal Register** Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Chyana Woodard,

Federal Register Liaison, Centers for Medicare & Medicaid Services.

[FR Doc. 2023–21460 Filed 9–28–23; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–D–3900]

Graft-Versus-Host Diseases: Developing Drugs, Biological Products, and Certain Devices for Prevention or Treatment; 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 ''Graft-versus-Host Diseases: Developing Drugs, Biological Products, and Certain Devices for Prevention or Treatment.'' The purpose of this guidance is to assist sponsors in the clinical development of drugs, biological products, and certain devices for the prevention or treatment of acute graft-versus-host disease (aGVHD) or chronic graft-vs-host disease (cGVHD). Specifically, this guidance addresses FDA's current thinking regarding the overall clinical development program and critical design elements for early and late phase trials for the intended populations. This guidance focuses on clinical trial design, statistical analysis, or other issues specific to aGVHD or cGVHD, and it does not contain a discussion of the general principles regarding statistical analysis, clinical trial design, or drug development. Additionally, this guidance is not intended to provide advice on the technical aspects of therapeutic or cell-processing devices.

DATES: Submit either electronic or written comments on the draft guidance by November 28, 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–3900 for ''Graft-versus-Host Diseases: Developing Drugs and Biological Products for Prevention or Treatment.'' 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 and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002; to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002; or to the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Robert Le, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 2124, Silver Spring, MD 20993, 240–402–8320, or Anne Taylor, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7256, Silver Spring, MD 20993, 240–402–5683.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Graft-versus-Host Diseases: Developing Drugs, Biological Products, and Certain Devices for Prevention or Treatment.'' The purpose of this guidance is to assist sponsors in the clinical development of drugs, biological products, and certain devices for the prevention or treatment of aGVHD or cGVHD. Specifically, this guidance addresses FDA's current thinking regarding the overall clinical development program and critical design elements for early and late phase trials for the intended populations.

aGVHD and cGVHD are clinical syndromes that may arise after allogeneic hematopoietic stem cell transplantation as a result of

immunocompetent donor cells recognizing and reacting to disparity with major or minor histocompatibility antigens on recipient tissues. The classical approach to prevention of GVHD involves pharmacological or physical methods to delete alloreactive T cells in the immediate peritransplant setting with or without additional drugs to prevent activation of naive T cells. Should aGVHD or cGVHD occur despite these measures, treatment has depended largely on drugs that impair T cells. Further basic science investigations have elucidated the molecular mechanisms behind the clinical manifestations of aGVHD and cGVHD, including cytokines, the innate immune system, and components of the adaptive immune system other than T cells. These scientific advances have provided opportunities for development of biomarkers to identify the specific immune dysfunction present in an individual patient and for development of drugs to modulate the immune system with precision rather than to just suppress the immune system globally.

Given the complexity of the clinical manifestation of aGVHD and cGVHD and the potential for a paradigm shift in the management of GVHD, this guidance provides recommendations regarding the design and conduct of clinical trials and the types of supporting data that could facilitate efficient development of drugs and/or certain devices for the prevention or treatment of aGVHD or cGVHD. This guidance also provides recommendations on what should be included in the marketing application to facilitate review.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Graft-versus-Host Diseases: Developing Drugs, Biological Products, and Certain Devices for Prevention or Treatment.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014; the collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001; the collections of information in 21 CFR part 601 have been approved under OMB control number 0910–0338; the collections of information in 21 CFR part 812 have been approved under OMB control number 0910–0078; and the collections of information in 21 CFR parts 50 and 56 have been approved under OMB control number 0910–0130.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: September 26, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–21524 Filed 9–28–23; 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 Recalls

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, the Agency, 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 October 30, 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, 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 part 107 (21 CFR part 107): Infant Formula.

In the **Federal Register** of October 6, 2022 (87 FR 60689), we provided notice communicating updates to the information collection and invited public comment on the proposed