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This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Graft-versus-Host Diseases: Developing Drugs, Biological Products, and Certain Devices for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]

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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

collections of information. No comments were received. On our own initiative, for efficiency of Agency operations, we are again revising the information collection to include related activities applicable to regulations in part 107, subpart E (21 CFR 107.200 through 107.280) pertaining to infant formula recalls. These information collections are currently approved in OMB control number 0910–0188. Specifically, 21 CFR 107.230 requires manufacturing firms conducting infant formula recalls to:

(1) evaluate the hazard to human health;

(2) devise a written recall strategy;

(3) promptly notify each affected direct account (customer) about the recall; and

(4) furnish the appropriate FDA district office with copies of these documents.

If the recalled formula presents a risk to human health, the recalling firm must also request that each establishment that sells the recalled formula post (at point of purchase) a notice of the recall and provide FDA with a copy of the notice.

Similarly, Agency regulations in 21 CFR 107.240 require recalling firms to:

(1) notify the appropriate FDA district office of the recall by telephone within 24 hours;

(2) submit a written report to that office within 14 days; and

(3) submit a written status report at least every 14 days until the recall is terminated. Before terminating a recall, recalling firms are required to submit a recommendation for termination of the recall to the appropriate FDA district office and wait for written FDA concurrence (21 CFR 107.250). Where the recall strategy or implementation is determined to be deficient, FDA may require the firm to change the extent of the recall, carry out additional effectiveness checks, and issue additional notifications (21 CFR 107.260). Finally, to facilitate identifying the location of the product being recalled, the recalling firm is required to maintain distribution records for at least 1 year after the expiration of the shelf life of the infant formula (§ 107.280 (21 CFR 107.280)).

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section; activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
107.230; Elements of infant formula recall	2	1	2	4,450	8,900
107.240; Notification requirements	2	1	2	1,482	2,964
107.250; Termination of infant formula recall	2	1	2	120	240
107.260; Revision of an infant formula recall	1	1	1	625	625
Total					12,729

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

The reporting and third-party disclosure burden estimates are based on current available data showing eight manufacturers of infant formula and that there have been, on average, two infant formula recalls per year for the past 3 years. Under 5 CFR 1320.3(b)(2), the time, effort, and financial resources necessary to comply with a collection of information are excluded from the burden estimate if the reporting, recordkeeping, or disclosure activities needed to comply are usual and customary because they would occur in the normal course of activities. Accordingly, because we believe that associated records are maintained as a usual and customary part of normal business activities, we include no separate burden estimate for recordkeeping requirements found in § 107.280.

TABLE 2—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

21 CFR section; activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
107.230; Elements of infant formula recall	2	1	2	50	100
107.260; Revision of an infant formula recall	1	1	1	25	25
Total					125

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

Although we have increased the number of respondents to the information collection since our last request for OMB approval, we have made no adjustments to the burden we estimate for the time necessary to complete activities associated with infant formula recalls.

Dated: September 26, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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