and the Pediatric Research Equity Act (Pub. L. 108–155) were made permanent under Title V of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144) (FDASIA). FDASIA requires that all BPCA requests for pediatric drug studies include a rationale for not including neonatal studies if none are requested.

Given that most drugs used in neonatal intensive care units (NICUs) are used in an off-label capacity, it is important that drug information be obtained in neonates to address gaps in neonatal labeling. In addition, therapies need to be developed for conditions unique to neonates. New approaches to the study of drugs in neonates should consider the diversity of the patient population and underlying conditions that are cared for in NICUs. Therefore, this guidance addresses subgroup classifications of neonates; general pharmacokinetic, pharmacodynamic, and pharmacogenomic considerations for clinical pharmacology studies in neonates; and clinical pharmacology considerations for planned studies in neonates.

This guidance finalizes the draft guidance entitled ''General Clinical Pharmacology Considerations for Neonatal Studies for Drugs and Biological Products'' issued on August 1, 2019 (84 FR 37653). FDA considered comments received on the draft guidance as the guidance was finalized. Changes from the draft to the final guidance include the addition of a section addressing immunogenicity, additional text regarding consideration of the total volume administered to neonates, and additional clarity regarding the use of microsampling methodology. In addition, editorial changes were made to improve clarity.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''General Clinical Pharmacology Considerations for Neonatal Studies for Drugs and Biological Products.'' 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 refers to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information related to institutional review boards in 21 CFR part 56 have been approved under OMB control number 0910–0130. The collections of information in 21 CFR part 314 for the submission of new drug applications have been approved under OMB control number 0910–0001. The collections of information in 21 CFR part 601 for the submission of biologics license applications have been approved under OMB control number 0910–0338. The collections of information 21 CFR part 312 for the submission of investigational new drug applications have been approved under OMB control number 0910–0014. The collections of information in §§ 312.47 and 312.82 for requesting meetings with FDA about drug development programs have been approved under OMB control number 0910–0429. The collections of information for the submission of prescription drug labeling in 21 CFR 201.56 and 21 CFR 201.57 have been approved under OMB control number 0910–0572.

III. Electronic Access

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

Dated: July 21, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–16076 Filed 7–26–22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2011–D–0125 and FDA–2021–N–0132]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approvals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of information collections that have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The following is a list of FDA information collections recently approved by OMB under section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507). The OMB control number and expiration date of OMB approval for each information collection are shown in table 1. Copies of the supporting statements for the information collections are available on the internet at *https://www.reginfo.gov/public/do/PRAMain.* An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

TABLE 1—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB

Title of collection	OMB control No.	Date approval expires
Establishing That a Tobacco Product Was Commercially Marketed in the United States As of February 15, 2007	0910–0775	7/31/2025
Study of How Consumers Use Flavors to Make Inferences About Electronic Nicotine Delivery System (ENDS) Product Qualities and Intentions to Use (Phase 2)	0910–0907	7/31/2025

Dated: July 21, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–16075 Filed 7–26–22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–1302]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Registration of Food Facilities

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 August 26, 2022.

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 0910–0502. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Rachel Showalter, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 240–994–7399, *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.

Registration of Food Facilities

OMB Control Number 0910–0502—Extension

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) (Pub. L. 107–188) amended the Federal Food, Drug, and Cosmetic Act (FD&C Act), to require, among other things, domestic and foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States to register with FDA. Sections 1.230 to 1.235 of our regulations (21 CFR 1.230 to 1.235) set forth the requirements for the registration of food facilities. Information provided to us under these regulations helps us to quickly notify the facilities that might be affected by a deliberate or accidental contamination of the food supply. In addition, data collected through registration is used to support FDA enforcement activities and to screen imported food shipments.

Advance notice of imported food allows FDA, with the support of the Bureau of Customs and Border Protection, to target import inspections more effectively and help protect the nation's food supply against terrorist acts and other public health emergencies. If a facility is not registered or the registration for a facility is not updated when necessary, we may not be able to contact the facility and may not be able to target import inspections effectively in case of a known or potential threat to the food supply or other food-related emergency, putting consumers at risk of consuming hazardous food products that could cause serious adverse health consequences or death.

To assist respondents of the information collection, we developed the following forms. Each facility that manufactures, processes, packs, or holds food for human or animal consumption in the United States must register with FDA using Form FDA 3537 entitled ''Food Facility Registration'' (§ 1.231), unless exempt under 21 CFR 1.226 from the requirement to register. To cancel a registration, respondents must use Form FDA 3537a entitled ''Cancellation of Food Facility Registration'' (§ 1.235). The terms ''Form FDA 3537'' and ''Form FDA 3537a'' refer to both the paper version of each form and the electronic system known as the Food Facility Registration Module, which is available at *https://www.access.fda.gov.* Registrations, updates, and cancellations are required to be submitted electronically. Domestic facilities are required to register whether or not food from the facility enters interstate commerce. Foreign facilities that manufacture, process, pack, or hold food also are required to register unless food from that facility undergoes further processing (including packaging) by another foreign facility outside the United States. However, if the further manufacturing/processing conducted by the subsequent facility consists of adding labeling or any similar activity of a de minimis nature, the former facility is required to register. In addition to the initial registration requirements, a facility is required to submit timely updates within 60 days of a change to any required information on its registration form, using Form FDA 3537 (§ 1.234), and to cancel its registration when the facility ceases to operate or is sold to new owners or ceases to manufacture, process, pack, or hold food for consumption in the United States, using Form FDA 3537a (§ 1.235).

Registration is one of several tools under the Bioterrorism Act that enables us to act quickly in responding to a threatened or actual bioterrorist attack on the U.S. food supply or other food-related emergency. Further, in the event of an outbreak of foodborne illness, the information provided helps us determine the source and cause of the event and enables us to quickly notify food facilities that might be affected by an outbreak, terrorist attack, or other emergency. Finally, the registration requirements enable us to quickly identify and remove from commerce an article of food for which there is a reasonable probability that the use of, or exposure to, such article of food will cause serious adverse health consequences or death to humans or animals.

Description of Respondents: Respondents to this collection of information are owners, operators, or agents in charge of domestic or foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States.

In the **Federal Register** of January 13, 2022 (87 FR 2159), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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