Final Orders under section 505G of the FD&C Act. In addition, consistent with the statutory requirement under section 505G(l)(4), the OMUFA commitment letter explains that FDA will issue guidance on its views regarding best practices for consolidated proceedings for appeals.

For administrative efficiency, rather than amend the existing FDR guidance to include FDR procedures for Final Orders and issue a separate guidance for consolidated proceedings for appeals, FDA is issuing this single guidance. This guidance addresses the process for resolving scientific and/or medical disputes of Final Orders, including FDR, administrative hearings, and consolidated proceedings. FDA has incorporated recommendations from the existing FDR guidance as appropriate.

This guidance finalizes the draft guidance entitled ''Formal Dispute Resolution and Administrative Hearings of Final Administrative Orders Under Section 505G of the Federal Food, Drug, and Cosmetic Act'' issued on June 23, 2023 (88 FR 41107). FDA considered comments received on the draft guidance as the guidance was finalized. Changes from the draft guidance to the final guidance include: (1) clarifying that the recommendations in this guidance are limited to FDR in accordance with section 505G(b)(2)(A)(iv)(III) and 505G(b)(4)(D)(iii) of the FD&C Act and to hearings in accordance with section 505G(b)(3) of the FD&C Act, and (2) removing language implying that new information could be submitted outside of, but at the same time or during, the FDR to avoid any suggestion that an eligible requestor or sponsor submitting a request for FDR should actively engage with other entities within FDA or pursue other regulatory or legal pathways on the same matter at the same time.

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 ''Formal Dispute Resolution and Administrative Hearings of Final Administrative Orders Under Section 505G of the Federal Food, Drug, and Cosmetic Act.'' 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. FDA considered the applicability of Executive Order 14192, per Office of Management and Budget (OMB) guidance in M–25–20, and finds this action to be deregulatory in nature.

II. Paperwork Reduction Act of 1995

Under section 505G(o) of the FD&C Act, the Paperwork Reduction Act of 1995 (PRA) does not apply to collections of information made under section 505G of the FD&C Act. The information collections made in this guidance implement the provisions of the following subsections of 505G:

(1) Section 505G(l)(4), which requires FDA to issue guidance that specifies the consolidated proceedings for appeal and the procedures for such proceedings where appropriate;

(2) Section 505G(b)(2)(A)(iv)(III), which requires that FDA afford requesters of drugs that will be subject to final administrative orders the opportunity for FDR up to the level of the Director of CDER;

(3) Section 505G(b)(3) and section 505G(b)(4)(E), which allow persons who participated in each stage of FDR with respect to a drug to request a hearing concerning a final administrative order with respect to such drug. Under section 505G(b)(3)(C)(ii), a single hearing may be conducted if more than one request is submitted with respect to the same administrative order; and

(4) Section 505G(j), which requires that all submissions be in electronic format.

Therefore, clearance by OMB under the PRA (44 U.S.C. 3501–3521) is not required for these collections of information.

In addition, this guidance refers to previously approved FDA collections of information. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information for over-the-counter (OTC) monograph products, OTC monograph order requests, and the OTC Monograph User Fee Program have been approved under OMB control number 0910–0340. The collections of information for FDR have been approved under OMB control number 0910–0001. The collections of information in 21 CFR 10.65 relating to meetings and correspondence have been approved under OMB control number 0910–0191.

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,* or *https://www.regulations.gov.*

Lowell M. Zeta,

Acting Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–23707 Filed 12–22–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–1210]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Postmarket Surveillance of Medical Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) 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 January 21, 2026.

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 0910–0449. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Barrett, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *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.

Postmarket Surveillance of Medical Devices—21 CFR Part 822

OMB Control Number 0910–0449—Extension

This information collection supports FDA regulations. Section 522 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360l) authorizes FDA to require a manufacturer to conduct postmarket surveillance (PS) of any device that meets the criteria set forth in the statute. The PS regulation establishes procedures that FDA uses to approve and disapprove PS plans. The regulation provides instructions to manufacturers, so they know what information is required in a PS plan submission. FDA reviews PS plan submissions in accordance with 21 CFR 822.15 through 822.19 of the regulation, which describe the grounds for approving or disapproving a PS plan. In addition, the PS regulation provides instructions to manufacturers to submit interim and final reports in accordance with 21 CFR 822.38. To assist respondents with understanding the applicable statutory and regulatory requirements, we also developed the interpretive agency guidance entitled, ''Postmarket Surveillance Under Section 522 of the Federal Food, Drug, and Cosmetic Act'' (October 2022) (available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/postmarket-surveillance-under-section-522-federal-food-drug-and-cosmetic-act*). Respondents to this collection of information are those manufacturers that require PS of their products.

In the **Federal Register** of June 6, 2025 (90 FR 25318) FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR part/activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
§§ 822.9 and 822.10; PS submission	3	1	3	120	360
§ 822.21; Changes to PS plan after approval	8	1	8	40	320
§ 822.28; Changes to PS plan for a device that is no longer marketed	1	1	1	8	8
§ 822.29; Waiver	1	1	1	40	40
§ 822.30; Exemption request	1	1	1	40	40
§ 822.38; Periodic reports	35	3	105	40	4,200
Total					4,968

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR part/activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
§ 822.31; Manufacturer records	3	1	3	20	60
§ 822.32; Investigator records	9	1	9	5	45
Total	105				

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

Our estimated burden for the information collection reflects an increase of 1,890 total burden hours and a corresponding increase 45 total annual responses. This increase is based on internal FDA tracking data. The number of respondents varies annually, subject to the number of original plans, plan changes, and interim and final reports (which are dependent on enrollment progress for each study) received by FDA.

Brian Fahey,

Associate Commissioner for Legislation.

[FR Doc. 2025–23630 Filed 12–22–25; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

[OS–0990–0488]

Agency Information Collection Request; 60-Day Public Comment Request

AGENCY: Office of the Secretary, Administration for Strategic Preparation and Response (ASPR), U.S. Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Administration for Strategic Preparation and Response (ASPR), HHS, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the information collection request (ICR) must be received on or before February 23, 2026.

ADDRESSES: Submit your comments to *wayland.coker@hhs.gov* or by calling (202) 875–1103.

FOR FURTHER INFORMATION CONTACT: When submitting comments or requesting information, please include the document identifier OS–0990–0488, and project title for reference, and send to Wayland Coker, the ASPR Center for Industrial Base Management and Supply Chain, Chief Supply Chain Strategist, *wayland.coker@hhs.gov,* or call (202) 875–1103.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and