

the comment must include the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. See FTC Rule 4.9(c). Your comment will be kept confidential only if the General Counsel grants your request in accordance with the law and the public interest. Once your comment has been posted publicly at www.regulations.gov, we cannot redact or remove your comment unless you submit a confidentiality request that meets the requirements for such treatment under FTC Rule 4.9(c), and the General Counsel grants that request.

The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding, as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before February 23, 2026. For information on the Commission's privacy policy, including routine uses permitted by the Privacy Act, see <https://www.ftc.gov/site-information/privacy-policy>.

Josephine Liu,

Assistant General Counsel for Legal Counsel.

[FR Doc. 2025-23696 Filed 12-22-25; 8:45 am]

BILLING CODE 6750-01-P

GENERAL SERVICES ADMINISTRATION

[OMB Control No. 3090-0315; Docket No. 2025-0001; Sequence No. 20]

Information Collection; Ombudsman Inquiry/Request Instrument

AGENCY: Office of Acquisition Policy, Office of the Procurement Ombudsman (OPO), General Services Administration (GSA).

ACTION: Notice and request for comments.

SUMMARY: Under the provisions of the Paperwork Reduction Act, the Regulatory Secretariat Division will be submitting to the OMB a request to review and approve a reinstatement of an information collection requirement regarding OMB Control No: 3090-0315; Ombudsman Inquiry/Request Instrument.

DATES: Submit comments on or before February 23, 2026.

ADDRESSES: Submit comments regarding this collection via <http://www.regulations.gov> and follow the instructions on the site. Submit comments via the Federal eRulemaking portal by searching the OMB control number. Select the link "Comment Now" that corresponds with

"Information Collection 3090-0315." Please include your name, company name (if any) and "Information Collection 3090-0315, Ombudsman Inquiry Request/Request Instrument" on your attached document.

Instructions: Please submit comments only and cite Information Collection 3090-0315; Ombudsman Inquiry/Request Instrument, in all correspondence related to this collection. Comments received generally will be posted without change to <http://www.regulations.gov>, including any personal and/or business confidential information provided. To confirm receipt of your comment(s), please check www.regulations.gov, approximately two-to-three days after submission to verify posting. If there are difficulties submitting comments, contact the GSA Regulatory Secretariat Division at GSARegSec@gsa.gov.

FOR FURTHER INFORMATION CONTACT: Frederick Landry, GSA Procurement Ombudsman & Industry Liaison, at telephone 202-501-4755.

SUPPLEMENTARY INFORMATION:

A. Purpose

The online intake Instrument on the GSA Ombudsman's web page receives inquiries from vendors who are currently doing business with or interested in doing business with GSA. The inquiries are collected by the GSA Ombudsman and routed to the appropriate office for resolution and/or implementation in the case of recommendations for process or program improvements. Reporting of the data collected helps highlight thematic issues that vendors encounter with GSA acquisition programs, processes, or policies, and identify areas where training is needed. The information collected also assists in identifying and analyzing patterns and trends to help improve efficiencies and lead to improvements in current practices.

B. Annual Reporting Burden

Maximum Potential Respondents: 118.

Responses per Respondent: 1.

Total Maximum Potential Annual

Responses: 118.

Hours per Response: .25.

Total Burden Hours: 29.5.

C. Public Comments

Public comments are particularly invited on: Whether this collection of information is necessary, whether it will have practical utility; whether our estimate of the public burden of this collection of information is accurate, and based on valid assumptions and methodology; ways to enhance the quality, utility, and clarity of the

information to be collected; and ways in which we can minimize the burden of the collection of information on those who are to respond, through the use of appropriate technological collection techniques or other forms of information technology.

Obtaining Copies: Requesters may obtain a copy of the information collection documents from the GSA Regulatory Secretariat Division at GSARegSec@gsa.gov. Please cite OMB Control No. 3090-0315, Ombudsman Inquiry/Request Instrument, in all correspondence.

Obtaining Copies of Proposals: Requesters may obtain a copy of the information collection documents from the GSA Regulatory Secretariat Division, by calling 202-501-4755 or emailing GSARegSec@gsa.gov. Please cite "Information Collection 3090-0315, Ombudsman Inquiry/Request Instrument", in all correspondence.

Nicole Bynum,

Regulatory Program Specialist, General Services Administration.

[FR Doc. 2025-23718 Filed 12-22-25; 8:45 am]

BILLING CODE 6820-61-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2023-D-2204]

Formal Dispute Resolution and Administrative Hearings of Final Administrative Orders Under Section 505G of the Federal Food, Drug, and Cosmetic Act; 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 final guidance for industry entitled "Formal Dispute Resolution and Administrative Hearings of Final Administrative Orders Under Section 505G of the Federal Food, Drug, and Cosmetic Act." This guidance provides recommendations for industry and review staff on the formal dispute resolution (FDR) and administrative hearings procedures for resolving scientific and/or medical disputes between the Center for Drug Evaluation and Research (CDER) and requestors and sponsors of drugs that will be subject to a final administrative

order under section 505G of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (“Final Order”). This guidance finalizes the draft guidance of the same title issued on June 23, 2023.

DATES: The announcement of the guidance is published in the **Federal Register** on December 23, 2025.

ADDRESSES: You may submit either electronic or written comments on Agency guidances 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-2204 for “Formal Dispute Resolution and Administrative Hearings of Final Administrative Orders Under Section 505G of the Federal Food, Drug, and Cosmetic Act.” 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 this 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. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Suzanne Strayhorn, Center for Drug Evaluation and Research (HFD-600), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6317, Silver Spring, MD 20993, 240-402-4247.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled “Formal Dispute Resolution and Administrative Hearings of Final Administrative Orders Under Section 505G of the Federal Food, Drug, and Cosmetic Act.” This guidance provides recommendations for industry and review staff on the FDR and administrative hearings procedures for resolving scientific and/or medical disputes between CDER and requestors and sponsors of drugs that will be subject to a Final Order under section 505G of the FD&C Act (21 U.S.C. 355h).

Section 505G of the FD&C Act was added by the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) (Pub. L. 116-136), which was enacted on March 27, 2020. After FDA issues a Final Order in accordance with section 505G(b)(2) of the FD&C Act, FDA must afford eligible requestors or sponsors the opportunity for FDR and hearings on disputes over the Final Order. This guidance describes the FDR procedures for eligible requestors or sponsors that wish to appeal a scientific and/or medical issue related to a Final Order. This guidance also outlines the procedures for an administrative hearing related to a Final Order. Finally, as required by section 505G(l)(4) of the FD&C Act, this guidance describes the procedures for consolidated proceedings for FDR and hearings to resolve the scientific and/or medical disputes.

FDA agreed to specific performance goals and procedures described in the document “Over-the-Counter Monograph User Fee Program Performance Goals and Procedures—Fiscal Years 2018–2022,” commonly referred to as the OMFUFA commitment letter (the document can be accessed at <https://www.fda.gov/media/106407/download>, and the document with updated goal dates for fiscal years 2021–2025 can be accessed at <https://www.fda.gov/media/146283/download>). The OMFUFA commitment letter specifies that FDA will revise the guidance for industry and review staff entitled “Formal Dispute Resolution: Sponsor Appeals Above the Division Level” (existing FDR guidance), available at <https://www.fda.gov/media/126910/download>, to include circumstances and procedures under which FDR may be used with respect to

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](https://www.regulations.gov), 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.