4164-01-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 This guidance finalizes the draft guidance of the same title issued on June 23, 2023.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 **[INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

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

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