# Formal Dispute Resolution and Administrative Hearings of Final Administrative Orders Under Section 505G of the Food, Drug, and Cosmetic Act

Guidance for Industry

***DRAFT GUIDANCE***

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**U.S. Department of Health and Human Services**
**Food and Drug Administration**
**Center for Drug Evaluation and Research (CDER)**

**June 2023**
**Procedural**

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**U.S. Department of Health and Human Services**
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# Guidance for Industry



## I. INTRODUCTION

This guidance provides recommendations for industry and review staff on the formal dispute resolution and administrative hearings procedures for resolving scientific and/or medical disputes between the Center for Drug Evaluation and Research (CDER) and requestors[1] and sponsors[2] of drugs that will be subject to a final administrative order (final order) under section 505G of the Food, Drug, and Cosmetic Act (FD&C Act)(21 U.S.C. 355h). The drugs that this guidance covers are nonprescription drugs without approved new drug applications, which are governed by the provisions of section 505G (hereafter referred to as over-the-counter (OTC) monograph drugs[3]).[4] Specifically, this guidance describes the CDER formal dispute resolution (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 (hearing) related to a final order. Finally, this guidance describes the procedures for consolidated proceedings for FDR and hearings to resolve scientific and/or medical disputes related to final orders.

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

[1] *Requestor* is defined in section 505G(q)(3) of the FD&C Act as any person or group of persons marketing, manufacturing, processing, or developing a drug.

[2] *Sponsor* is defined in section 505G(q)(2) of the FD&C Act as any person marketing, manufacturing, or processing a drug that is listed pursuant to section 510(j) of the FD&C Act and is or will be subject to an administrative order under section 505G of the FD&C Act.

[3] See section 744L(5) of the FD&C Act.

[4] This guidance does not apply to internal disputes involving FDA staff.

## II. BACKGROUND

### A. Regulatory Framework

On March 27, 2020, the president signed into law the Coronavirus Aid, Relief, and Economic Security Act (CARES Act). The CARES Act added section 505G to the FD&C Act. Section 505G reforms and modernizes the framework for the regulation of OTC monograph drugs. OTC monograph drugs may be marketed without an approved drug application under section 505 of the FD&C Act if they meet the requirements of section 505G of the FD&C Act, as well as all other applicable requirements.

The CARES Act also added section 744M to the FD&C Act authorizing FDA to assess and collect user fees dedicated to OTC monograph drug activities.

Under the process set forth in section 505G(b) of the FD&C Act, FDA has the authority to issue orders (proposed and final) that add, remove, or change generally recognized as safe and effective (GRASE) conditions for OTC drug monographs.[5] Either FDA or a requestor can initiate the order process.[6] A requestor can initiate the order process by submitting an OTC monograph order request (OMOR)[7] with respect to certain drugs, classes of drugs, or combinations of drugs.[8]

After FDA issues a final order in accordance with section 505G(b)(2) of the FD&C Act, FDA must afford requestors of drugs that will be subject to such an order the opportunity for FDR up to the level of the Director of CDER.[9] FDR begins at the management level in the CDER chain of command above the level where the decision was made. Similarly, after FDA issues a final order in an expedited procedure under section 505G(b)(4) of the FD&C Act, FDA must afford sponsors of drugs that will be subject to such an order the opportunity for FDR up to the level of the Director of CDER.[10]

[5] See section 505G(b) of the FD&C Act.

[6] See section 505G(b)(1)(A) of the FD&C Act.

[7] See section 744L(7) of the FD&C Act which defines an OTC monograph order request as a request submitted under section 505G(b)(5) of the FD&C Act.

[8] See section 505G(b)(5) of the FD&C Act.

[9] See section 505G(b)(2)(A)(iv)(III) of the FD&C Act.

[10] See section 505G(b)(4)(D)(iii) of the FD&C Act.

If an eligible requestor or sponsor has participated in each stage of FDR up to the level of the Director of CDER and remains unsatisfied with CDER's decision, the eligible requestor or sponsor may request a hearing.[11]

If more than one request for FDR or a hearing is submitted with respect to the same final order, FDA may consolidate the requests and direct that a single proceeding be conducted for FDR and the hearing.[12] Section 505G(l)(4) of the FD&C Act requires FDA to issue guidance on consolidated proceedings for appeal and the procedures for such proceedings. This guidance, including section V., fulfills this requirement.

### B. Over-the-Counter Monograph User Fee Program Performance Goals and Procedures

The Over-the-Counter Monograph User Fee Program Performance Goals and Procedures document, commonly referred to as the OMUFA commitment letter, specifies FDA and industry mutually agreed-upon timelines for FDR, as described in this guidance.[13] The OMUFA commitment letter does not specify timelines for hearings.

The OMUFA commitment letter specifies that FDA will revise the guidance for industry and review staff *Formal Dispute Resolution: Sponsor Appeals Above the Division Level* (November 2017)[14] (2017 FDR guidance) 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 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 appeal, FDA is issuing this single guidance. This guidance addresses the process for resolving scientific and/or medical disputes between CDER and requestors and sponsors of drugs that will be subject to final orders, including FDRs, hearings, and consolidated proceedings.[15] FDA has incorporated recommendations from the existing FDR guidance as appropriate.

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[11] See section 505G(b)(3) of the FD&C Act.

[12] See section 505G(b)(3)(C)(ii) and section 505G(l)(4) of the FD&C Act.

[13] Available at https://www.fda.gov/media/106407/download. Per the statutory authority for OMUFA fees enacted under the CARES Act, FDA updated the OMUFA goal dates to reflect that FY 2021 is OMUFA's first program year. The updated goal dates are available at https://www.fda.gov/media/146283/download.

[14] We update guidances periodically. For the most recent version of a guidance, check the FDA guidance web page at https://www.fda.gov/regulatory-information/search-fda-guidance-documents.

[15] This guidance does not address judicial review.

# III. FORMAL DISPUTE RESOLUTION OF FINAL ORDERS

## A. Considerations Before Submitting a Request for FDR

### *1. Who Is Eligible to Request FDR?*

Requestors of OTC monograph drugs that will be subject to the final order issued in accordance with section 505G(b)(2)(A)(iv)(I) of the FD&C Act (hereafter referred to as eligible requestors) are eligible to request FDR under section 505G(b)(2)(A)(iv)(III).

Sponsors of OTC monograph drugs that will be subject to a final order issued in an expedited procedure in accordance with section 505G(b)(4)(D)(i) of the FD&C Act (hereafter referred to as eligible sponsors) are eligible to request FDR under section 505G(b)(4)(D)(iii).

### *2. What Is an Appropriate Matter for FDR?*

After FDA issues a final order, FDA is required to afford eligible requestors or sponsors the opportunity for FDR up to the level of the Director of CDER.[16,17] As set forth in the 2017 FDR guidance, FDA has provided formal dispute resolution "to address scientific and/or medical disputes between a sponsor and CDER or [the Center for Biologics Evaluation and Research] as such disputes relate to the sponsor's application for a product covered by user fee goals (user fee products)."[18] Accordingly, FDA believes that FDR pursuant to section 505G(b)(2)(A)(iv)(III) is appropriate for scientific and/or medical disputes related to a determination in a final order whether there are conditions under which a specific drug, a class of drugs, or a combination of drugs is determined to be (1) not subject to section 503(b)(1) of the FD&C Act, which requires certain drugs to be dispensed by prescription only, and (2) generally recognized as safe and effective under section 201(p)(1) of the FD&C Act, which provides, with certain exceptions, that a drug is a "new drug" if it is "not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof."[19]

### *3. What Is Not Appropriate for FDR?*

The issuance of a proposed order[20] or an interim final order[21] is not a final order and therefore would not be appropriate for FDR.

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[16] See section 505G(b)(2)(A)(iv)(III) and section 505G(b)(4)(D)(iii) of the FD&C Act.

[17] FDR begins at the next management level in the CDER chain of command above the level at which the decision being appealed was made and proceeds up to the level of the Director of CDER.

[18] See section II. A., Regulatory Framework, of the 2017 FDR guidance.

[19] See section 505G(b)(2)(A)(ii)(I) of the FD&C Act.

[20] See section 505G(b)(2)(A)(ii)(I) of the FD&C Act.

[21] See section 505G(b)(4)(A)(i)(I) and section 505G(b)(4)(B)(i)(II) of the FD&C Act.

Meeting minutes and other correspondences that communicate advice are not final orders and therefore would not be appropriate subjects for a request for FDR by an eligible requestor or sponsor. FDA communications, such as meeting minutes or other correspondences (e.g., general advice letters), typically include recommendations and/or advice made to a requestor or sponsor that generally conveys CDER's current thinking on a particular topic raised by the requestor or sponsor. Requestors and sponsors are not bound by such recommendations and/or advice. Requestors and sponsors can follow the advice in meeting minutes or other correspondences, or they can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations.

To ensure efficient use of FDA resources, the eligible requestor or sponsor submitting a request for FDR should not actively engage with other entities within FDA or pursue other regulatory or legal pathways on the same matter at the same time.

### *4. Is There a Specific Timeline to Request FDR?*

For FDR with respect to a final order issued in accordance with 505G(b)(2) of the FD&C Act, an eligible requestor must submit the request for FDR within 45 calendar days of the issuance of the final order. For subsequent levels of appeal, an eligible requestor must submit the request for FDR within 30 calendar days of the prior decision.[22]

For FDR with respect to a final order under section 505G(b)(4) of the FD&C Act, an eligible sponsor must submit the request for FDR within 45 calendar days of the issuance of the final order. For subsequent levels of appeal, an eligible sponsor must submit the request for FDR within 30 calendar days of the prior decision.[23] FDA must complete any hearings for the final order issued in an expedited procedure under section 505G(b)(4) of the FD&C Act not later than 12 months after the date on which the final order is issued.[24] Therefore, FDA must specify in an interim final order issued under section 505G(b)(4) if shorter periods for requesting FDR are necessary to meet the 12-month timeline for completing a hearing.[25]

### *5. May New Information or New Analyses of Previously Reviewed Data Be Included in a Request for FDR?*

Because internal FDA review of a decision that has been appealed by an eligible requestor or sponsor should be based on the same information as was relied on to make the original decision (i.e., information already in the relevant administrative file, including public comments submitted during the public comment period for the proposed order), no new information

[22] See section 505G(b)(2)(A)(iv)(III) of the FD&C Act.

[23] See section 505G(b)(4)(D)(iii) of the FD&C Act.

[24] See section 505G(b)(4)(F)(i)(II) of the FD&C Act.

[25] See section 505G(b)(4)(F)(ii) of the FD&C Act.

should be submitted as part of a request for FDR.[26] CDER regards new or updated analyses of previously reviewed data to be new information because the original deciding official might have made a different decision had he or she had the opportunity to review the new analyses.

### *6. Is FDR and the Information Submitted to FDA in Connection with FDR Confidential?*

Section 505G(d) of the FD&C Act addresses the confidentiality of information submitted to FDA in connection with proceedings on an order, including FDR under section 505G(b).[27] The OTC monograph order processes under section 505G(b) of the FD&C Act are generally public processes.[28] Except to the extent public disclosure of information submitted to FDA is prohibited, the Agency generally intends to make information submitted to FDA in the context of FDR, which may include a request for FDR or information submitted to FDA in support thereof, available to the public upon submission.[29]

Under section 505G(d)(2)(B), information submitted in connection with FDR will remain confidential if (1) the information pertains to pharmaceutical quality information, unless such information is necessary to establish standards under which a drug is GRASE, or (2) the information is of the type contained in raw datasets.[30]

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[26] If an eligible requestor or sponsor wants CDER to consider new information, including safety information, the new information should be submitted outside FDR. For example, new important safety information may be submitted as part of a Type X meeting submission, or new safety or efficacy data in support of a condition that FDA previously determined through a final order was non-GRASE may be submitted under an OMOR.

[27] Section 505G(d) consists of (1) a prohibition on FDA disclosure of certain information under section 505G(d)(1) without the requestor's consent, subject to (2) requirements that FDA make certain information publicly available under section 505G(d)(2)(A)(i) and (ii), subject to (3) limitations on FDA disclosing certain such information as described in section 505G(d)(2)(B)(i)-(iv).

[28] In general, section 505G(b) of the FD&C Act describes processes to determine whether there are conditions under which a drug, in relevant part, is "generally recognized as safe and effective under section 201(p)(1)." See section 505G(b)(1). Under section 201(p)(1), a "new drug," in relevant part, is a drug "the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof." It is well-settled that "general recogni[tion]" of safety and effectiveness under section 201(p)(1) requires, among other things, the information demonstrating that a drug is safe and effective for its intended use to be published so that such information is generally available to qualified experts. See, for example, *Weinberger v. Bentex Pharm., Inc.*, 412 U.S. 645, 652 (1973); *Tri-Bio Labs., Inc. v. United States*, 836 F.2d 135, 142 (3d Cir. 1987); *United States v. Articles of Drug . . . Promise Toothpaste*, 826 F.2d 564, 572-73 (7th Cir. 1987) (citing *United States v. An Article of Drug . . . 4,680 Pails*, 725 F.2d 976, 987 (5th Cir. 1984)); *United States v. Undetermined Quantities of . . . Equidantin Nitrofurantoin*, 675 F.2d 994, 1000-01 (8th Cir. 1982); *Premo Pharm. Labs., Inc. v. United States*, 629 F.2d 795, 802-03 (2d Cir. 1980); *United States v. An Article of Drug . . . Entrol-C Medicated*, 513 F.2d 1127, 1128 (9th Cir. 1975); *United States v. Hakim*, 462 F. Supp. 3d 418, 431 (S.D.N.Y. 2020); *United States v. Innovative BioDefense, Inc.*, 2019 WL 7195332 at *4 (C.D. Cal. Nov. 15, 2019).

[29] See section 505G(d)(2)(A)(i) and (ii).

[30] See section 505G(d)(2)(B)(i), (iv) of FD&C Act.

In addition, although certain information submitted in connection with FDR is to be made available to the public in accordance with section 505G(d) of the FD&C Act, any meeting held during FDR is not open to the public to attend, and only the eligible requestor or sponsor may be present at the meeting with FDA.[31]

### B. Procedures for Submitting a Request for FDR

#### *1. How to Request FDR*

An eligible requestor or sponsor should submit a request for FDR as described in this section and section III. B .2., Content and Format of a Request for FDR. Before an eligible requestor or sponsor submits a request, FDA strongly encourages the eligible requestor or sponsor to contact CDER and provide advance notice of the intent to submit a request for FDR to ensure prompt handling and, if applicable, consolidation of FDR requests (see section V., Consolidated Proceedings).

The request for FDR should be submitted to FDA via the CDER NextGen Portal.[32] An electronic copy of the request should also be submitted to the CDER Formal Dispute Resolution Project Manager (FDRPM).[33] CDER encourages eligible requestors and sponsors to contact the FDRPM before submitting the request.

#### *2. Content and Format of a Request for FDR*

A request for FDR should include information adequate to explain the nature of the scientific and/or medical dispute and to allow the deciding official to determine the necessary steps needed to resolve the matter. Each request should include the following:

- Identification of the submission as **FORMAL DISPUTE RESOLUTION REQUEST** in bold, uppercase letters
- The order identification (ID) number
- The OTC monograph ID number and OTC monograph title, if applicable
- The determination(s) in the final order that are the subject(s) of dispute, including the identification of specific OTC monograph provisions, if any, that are implicated

[31] 21 CFR 10.65(c).

[32] CDER's NextGen Portal is available at https://edm.fda.gov/EDMIDPLogin/welcome?response_type=code&client_id=0oa1as7rb2poiYTch297&scope=openid%20profile&state=876592757_1614020952133&redirect_uri=https%3A%2F%2Fedm.fda.gov%2Foidcclient%2Fedmrp.

[33] The contact information can be found on the CDER Formal Dispute Resolution web page, available at https://www.fda.gov/about-fda/cder-contact-information/cder-formal-dispute-resolution#:~:text=Formal%20Dispute%20Resolution%20(FDR)%20is,resolved%20at%20the%20division%20level.

- A brief but comprehensive statement of each issue to be resolved, including the following:
  - A description of the scientific and/or medical dispute to be resolved
  - A summary of relevant regulatory history, including any prior stage of FDR related to the same scientific and/or medical dispute, if applicable
  - A statement of the eligible requestor's or sponsor's proposed possible solutions and/or outcomes
- A statement identifying the division and/or office that issued the final order and, if applicable, the deciding official on any prior stage of FDR related to the same scientific and/or medical dispute
- A list of documents previously submitted as part of the eligible requestor's or sponsor's OMOR or public comments (including information and data) submitted during the public comment period for the proposed order that are deemed necessary for resolution of the matter, with reference to submission dates so the documents can be readily located
- A statement that no new information has been submitted in support of the request for FDR and, if applicable, that the last deciding official received and had the opportunity to review all of the material now being relied upon for FDR
- The name, title, and contact information (i.e., mailing address, email address, telephone number, fax number) for the eligible requestor's or sponsor's contact for the FDR

### C. FDA Action

The FDRPM functions as the administrative contact for all issues related to a request for FDR. The FDRPM is responsible for communicating and explaining to an eligible requestor or sponsor all regulatory processes related to FDR. FDA will conduct a preliminary review of the request to determine if it is timely and if the requestor or sponsor is eligible to request FDR.

#### *1. Letter Accepting or Not Accepting a Request for FDR*

If the eligible requestor's or sponsor's request for FDR is accepted, the FDRPM will forward the appeal to the appropriate CDER management level, as established under the CDER chain of command. The FDRPM will also send the eligible requestor or sponsor an acknowledgment letter identifying the deciding official, the due date for response, and the date of any meeting, if applicable.

If a request for FDR is not accepted, the FDRPM will send the eligible requestor or sponsor a letter on behalf of the deciding official identifying the reasons the request was not accepted.

### *2. Responses to an Accepted Request for FDR*

In general, the deciding official will send a written decision to an eligible requestor or sponsor that submits a request for FDR that is accepted for review. The written decision will grant or deny the appeal. If the deciding official does not agree with the eligible requestor's or sponsor's proposed outcome, he or she should provide the reasons for not agreeing with the eligible requestor's or sponsor's proposal and possibly suggest other options to achieve resolution and identify any actions that could be taken to address the concerns articulated by the deciding official. Before issuing a final decision, the deciding official may also provide an interim response (e.g., a request to clarify information in the request for FDR or a request for a meeting with the eligible requestor or sponsor) before making a decision on the appeal. The interim response should explain why an interim response is being issued instead of a final decision on the appeal.

### *3. Timelines for Reviewing an Accepted Request for FDR*

Consistent with the relevant timelines from the 2017 FDR guidance, the deciding official should complete his or her review and provide the eligible requestor or sponsor an interim response or a decision on the appeal within 30 calendar days from receipt of a request for FDR that has been accepted. The deciding official should respond to the eligible requestor or sponsor within the 30-day window in writing or by telephone (i.e., 30-day response). If the response is by telephone, the deciding official should follow up with a written confirmation within 14 calendar days of the verbal response.

For the deciding official to reach a decision, there may be instances when he or she needs additional clarifying information[34] or input from other persons knowledgeable about the specific matter in dispute or about the issue or area more generally. In such situations, the deciding official should issue the eligible requestor or sponsor an interim response identifying the additional information or input needed. The interim response should be made within 30 calendar days of receipt of the appeal.

- In instances when the deciding official needs clarifying information from the eligible requestor or sponsor, the deciding official should send the eligible requestor or sponsor a request for this information within 30 calendar days from receipt of the request for FDR. The deciding official should provide an interim response or a decision on the request within 30 calendar days from receipt of the clarifying information submitted by the eligible requestor or sponsor.

- In instances when the deciding official decides a meeting with the eligible requestor or sponsor is needed before an interim response or decision can be issued, the deciding official should send the eligible requestor or sponsor a request for a meeting within 30

[34] *Clarifying information* does not include new information or reanalysis of data that have not been reviewed by the division and/or office. As stated previously, FDA considers new analyses of previously reviewed data to be new information because the original deciding official might have made a different decision had he or she had the opportunity to review the new analyses.

calendar days from receipt of the eligible requestor's or sponsor's request for FDR. CDER should schedule any meetings as quickly as the eligible requestor or sponsor and CDER are able to agree on a mutually acceptable date and time. After the meeting is held, the deciding official should provide an interim response or a decision on the request to the eligible requestor or sponsor within 30 calendar days from the meeting date.

- In instances when the deciding official needs to discuss the request for FDR with internal or external experts, CDER should inform the eligible requestor or sponsor within 30 calendar days from receipt of the eligible requestor's or sponsor's request for FDR that the deciding official is seeking this additional input. CDER should schedule such discussions with internal or external experts as quickly as possible. After this discussion takes place, the deciding official should provide an interim response or a decision on the FDR to the eligible requestor or sponsor within 30 calendar days from the date of the discussion.

If the deciding official is unable to complete the review and provide either an interim response or a decision to the eligible requestor or sponsor within 30 calendar days, CDER should notify the eligible requestor or sponsor, explain the reasons for the delay, and provide the anticipated timeline for completing the review. In these cases, the performance goals outlined in the OMUFA commitment letter for the dispute response would not be met.

### D. Repeat Requests for FDR

If an eligible requestor's or sponsor's request for FDR is denied at one management level, the eligible requestor or sponsor can appeal the same matter to the next higher management level in the CDER chain of command up to the level of the Director of CDER.[35] For each appeal, a new request for FDR should be submitted to the next management level and should follow the process and timelines provided in this guidance.

## IV. ADMINISTRATIVE HEARING

Pursuant to section 505G of the FD&C Act, the hearing on a final order is held before a presiding officer designated by FDA.

Upon completion of FDR up to the Director of CDER, FDA will inform the eligible requestors and sponsors that participated in each stage of FDR of their right to request a hearing.[36]

[35] See section 505G(b)(2)(A)(iv)(III) and section 505G(b)(4)(D)(iii) of the FD&C Act.

[36] See section 505G(b)(2)(A)(iv)(IV) of the FD&C Act.

## A. Considerations Before Submitting a Request for a Hearing

### *1. Who Is Eligible to Request a Hearing?*

Upon completion of FDR up to the level of the Director of CDER, an eligible requestor or sponsor that participated in each stage of FDR may request a hearing concerning a final order unless the final order relates to certain drugs as specified in section 505G(b)(3)(B) of the FD&C Act. [37,38]

### *2. Who Is Not Eligible to Request a Hearing?*

A requestor or sponsor that did not participate in each stage of FDR may not request a hearing on a final order.

### *3. When Will FDA Not Provide Notice and an Opportunity for a Hearing?*

FDA will not provide notice and an opportunity for a hearing if (1) the final order involved relates to a drug that is described in section 505G(a)(3)(A) of the FD&C Act,[39] which applies to certain drugs that are classified in category III for safety or effectiveness in the preamble of a proposed rule establishing a tentative final monograph that is the most recently applicable proposal or determination for such drug issued under 21 CFR part 330, and (2) no human or non-human data studies[40] relevant to the safety or effectiveness of such a drug have been submitted to the administrative record since the issuance of the most recent tentative final monograph relating to such a drug.[41]

### *4. Is There a Specific Timeline to Request a Hearing?*

The eligible requestor or sponsor must submit the request for a hearing not later than 30 calendar days after receiving notice of the final decision of the FDR procedure.[42]

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[37] See section 505G(b)(3)(A) of the FD&C Act.

[38] See section 505G(b)(4)(E) of the FD&C Act.

[39] See section 505G(b)(3)(B)(i)(I) of the FD&C Act.

[40] The term *human data studies* means clinical trials of safety or effectiveness (including actual use studies), pharmacokinetics studies, or bioavailability studies. See section 505G(b)(3)(B)(ii)(I) of FD&C Act. The term *non-human data* means data from testing other than with human subjects which provides information concerning safety or effectiveness. See section 505G(b)(3)(B)(ii)(II) of the FD&C Act.

[41] See section 505G(b)(3)(B)(i)(II) of the FD&C Act.

[42] See section 505G(b)(3)(A) and section 505G(b)(3)(A) of the FD&C Act.

### *5. Is There a Specific Timeline for When a Hearing Must Be Complete?*

FDA must complete any hearings for a final order issued in an expedited procedure under section 505G(b)(4)(F) of the FD&C Act not later than 12 months after the date on which the final order is issued.

### *6. May New Information or New Analyses of Previously Reviewed Data Be Included in a Hearing Request?*

The eligible requestor or sponsor must submit a request for a hearing that is based solely on information in the administrative record.[43] Therefore, FDA will not consider new information or new analyses of previously reviewed data as evidence in a hearing.

### *7. Is a Hearing and the Information Submitted in Connection with a Hearing Confidential?*

Section 505G(d) of the FD&C Act addresses the confidentiality of information submitted to FDA in connection with proceedings on an order, including hearings under section 505G(b).[44] As noted above, the OTC monograph order processes under section 505G(b) of the FD&C Act are generally public processes.[45] Except to the extent public disclosure of information submitted to FDA is prohibited, the Agency generally intends to make information submitted to FDA in the context of a hearing, which may include a request for a hearing or information submitted to FDA in support thereof, available to the public upon submission.[46]

Under section 505G(d)(2)(B), information submitted in connection with a hearing will remain confidential if (1) the information pertains to pharmaceutical quality information, unless such information is necessary to establish standards under which a drug is GRASE, or (2) the information is of the type contained in raw datasets.[47]

## B. Procedures for Submitting a Request for a Hearing

### *1. How Does An Eligible Requestor or Sponsor Request a Hearing?*

After FDA informs an eligible requestor or sponsor of their right to request a hearing, the eligible requestor or sponsor can submit a request for a hearing as described below. Before the eligible requestor or sponsor submits a request for a hearing, FDA strongly encourages the eligible requestor or sponsor to contact FDA and provide advance notice of the intent to submit a request

[43] See section 505G(b)(3)(A) of the FD&C Act.

[44] See supra note 27.

[45] See supra note 28.

[46] See section 505G(d)(2)(A)(i), (ii) of the FD&C Act.

[47] See section 505G(d)(2)(B)(i), (iv) of the FD&C Act.

for a hearing to ensure prompt handling and, if applicable, consolidation of the hearing (see section V., Consolidated Proceedings).

The request for a hearing should be submitted to the FDA via the CDER NextGen Portal. FDA encourages the eligible requestor or sponsor to contact the Office of New Drugs in CDER before submitting the request for a hearing.

*2. What Is the Content and Format of a Request for a Hearing?*

The request for a hearing must be based solely on information in the administrative record.[48]

The request for a hearing should include the following:

- Identification of the submission as **OTC MONOGRAPH FINAL ORDER ADMINISTRATIVE HEARING REQUEST** in bold, uppercase letters
- The order ID number
- The OTC monograph ID number and OTC monograph title, if applicable
- The determination(s) in the final order that that are the subject(s) of dispute, including the identification of specific OTC monograph provisions, if any, that are implicated
- A brief but comprehensive statement of each issue to be resolved, including the following:
  - A description of what the requestor or sponsor contends is a genuine and substantial question of material fact justifying a hearing
  - A list of references to information in the administrative record that supports the hearing request, including submission dates, so the documents can be readily located
- A statement that no new information has been submitted in support of the request for a hearing
- The name, title, and contact information (i.e., mailing address, email address, telephone number, fax number) for the eligible requestor's or sponsor's contact for the request for a hearing

[48] See section 505G(b)(3)(A) of the FD&C Act.

### C. FDA Action in Response to Request for Hearing

FDA will conduct a preliminary review of a request for a hearing to determine if it is timely and if the requestor or sponsor is eligible to request a hearing.[49] If the requestor or sponsor is eligible and the request is timely, then the request for a hearing will be accepted and the Office of Scientific Integrity (OSI) within the Office of the Chief Scientist will send the eligible requestor or sponsor an acknowledgment letter. If the request for a hearing is not accepted, OSI will send a letter identifying the reasons the request for a hearing was not accepted.

If the eligible requestor's or sponsor's request for a hearing is accepted, FDA will decide whether to grant or deny it.

FDA may deny a request for a hearing if the request does not identify the existence of a genuine and substantial question of material fact. In making such a determination, FDA may consider only information and data that are based on relevant and reliable scientific principles and methodologies.[50]

### D. Hearing Procedure

Section 505G of the FD&C Act provides further detail on the hearing procedures as described in this section.

A hearing for a final order under section 505G of the FD&C Act is not a formal evidentiary hearing.[51]

#### *1. Public Hearing*

A hearing for a final order is generally public.

FDA expects rarely to close all or part of a hearing because the OTC monograph order processes under section 505G(b) of the FD&C Act are generally public processes and hearings are based solely on information in the administrative record. However, FDA may close all or part of the hearing to prevent the disclosure of information that FDA has held as confidential in the administrative record.

[49] Ibid.

[50] See section 505G(b)(3)(C)(i) of the FD&C Act.

[51] See section 505G(p) of the FD&C Act (providing that the requirements of subchapter II of the Administrative Procedure Act, which include requirements relating to formal hearings, shall not apply with respect to orders issued under section 505G of the FD&C Act).

494 *2. Presiding Officer*
495
496 If FDA grants a request for a hearing, a presiding officer will be appointed to conduct the
497 hearing.[52] The presiding officer will not be an employee of CDER or have been previously
498 involved in the development of the administrative order at issue or proceedings relating to that
499 administrative order.[53]
500
501 *3. Rights of Parties to Hearing*
502
503 The parties to a hearing have the right to present testimony, including testimony of expert
504 witnesses, and to cross-examine witnesses presented by other parties. When appropriate, the
505 presiding officer may require that cross-examination by parties representing substantially the
506 same interests be consolidated to promote efficiency and avoid duplication (see section V.,
507 Consolidated Proceedings).[54]
508
509 *4. Final Decision*
510
511 At the conclusion of the hearing, the presiding officer for the hearing will issue a decision
512 containing findings of fact and conclusions of law.[55] The decision of the presiding officer will be
513 final.[56]
514
515
516 **V. CONSOLIDATED PROCEEDINGS**
517
518 **A. Consolidation of Proceedings by FDA**
519
520 *1. Proceedings FDA May Consolidate*
521
522 If more than one request for FDR or a hearing is submitted with respect to the same final order,
523 FDA may consolidate the requests and direct that a single proceeding be conducted for FDR or a
524 hearing, as applicable.[57]
525
526 To promote efficiency and avoid duplication, generally, FDA expects that multiple requests for
527 FDR or hearings with respect to the same final order and, especially, with respect to the same
528 issue (e.g., a specific monograph condition) if multiple issues are being addressed under the
529 same order, will be consolidated into a single proceeding.

[52] See section 505G(b)(3)(C)(iii) of the FD&C Act.

[53] See section 505G(b)(3)(C)(iii) of the FD&C Act.

[54] See section 505G(b)(3)(C)(iv) of the FD&C Act.

[55] See section 505G(b)(3)(C)(v)(I) of the FD&C Act.

[56] Ibid.

[57] See section 505G(b)(3)(C)(ii) and section 505G(l)(4) of the FD&C Act.

Although all consolidated parties may participate in the FDR or hearing, the number of individuals from each party able to attend the consolidated proceedings in person may be limited because of facility and space limitations. FDA will determine the total number of individuals who can attend the consolidated proceedings in person.

*2. Notice of Consolidation*

FDA will provide written notification to all eligible requestors or sponsors detailing (1) that the FDR or hearing will be consolidated into a single proceeding in which all parties may participate and (2) a listing of the consolidated eligible requestors or sponsors.

### B. Consolidation of Proceedings by Eligible Parties

*1. Joint Request for FDR or a Hearing*

Eligible requestors or sponsors with respect to the same final order may submit a joint request for FDR or a hearing.

*2. Content and Format of Joint Request for FDR or a Hearing*

In addition to the information that is to be submitted in a request for FDR (see section III. B. 2., Content and Format of a Request for FDR) or a hearing (see section IV. B. 3, What Is the Content and Format of a Request for a Hearing?), a joint request for FDR or a hearing should include the following information:

- Identification of the submission as **CONSOLIDATED OTC MONOGRAPH FINAL ORDER FORMAL DISPUTE RESOLUTION REQUEST** or **CONSOLIDATED OTC MONOGRAPH FINAL ORDER HEARING REQUEST** in bold, uppercase letters

- List of eligible sponsors or requestors submitting the joint request

- The name of the point of contact as designated by the eligible requestors or sponsors submitting the joint request and appropriate documentation designating the point of contact

### C. Voluntary Termination of FDR and Hearing Process by Eligible Requestor or Sponsor in a Consolidated Proceeding

If an eligible requestor or sponsor participating in a consolidated proceeding no longer wants to continue with the FDR or hearing process, the eligible requestor or sponsor must submit notice to FDA to terminate their participation in the consolidated proceeding. Termination precludes the eligible requestor or sponsor from continuing in the FDR or hearing process; however, the FDR or hearing process may proceed with the other eligible requestors or sponsors.