Formal Meetings Between FDA and Sponsors or Requestors of Over-the-Counter Monograph Drugs

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DRAFT GUIDANCE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)

February 2022
Procedural

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TABLE OF CONTENTS

Formal Meetings Between FDA and Sponsors or Requestors of Over-the-Counter Monograph Drugs Guidance for Industry[1]

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. 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. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

I. INTRODUCTION

This guidance provides recommendations to industry on formal meetings between the Food and Drug Administration (FDA) and sponsors[2] or requestors[3] of nonprescription drugs without approved new drug applications that are governed by section 505G of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355h) (hereafter referred to as *OTC (over-the-counter) monograph drugs*[4]).[5] This guidance specifies the procedures and principles for formal meetings between FDA and sponsors or requestors for an OTC monograph drug (hereafter referred to collectively as *meeting requesters*).[6] In doing so, it describes procedures under which meeting requesters can meet with appropriate FDA officials to obtain advice on the studies and other information necessary to support submissions under section 505G of the FD&C Act, to obtain advice on other matters relevant to the regulation of nonprescription drugs, and to obtain advice on the development of new OTC monograph drugs.[7] This guidance also specifies

[1] This guidance has been prepared by the Office of Nonprescription Drugs in the Center for Drug Evaluation and Research at the Food and Drug Administration.

[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 FD&C Act 510(j) and is or will be subject to an administrative order under section 505G of the FD& Act. When this guidance uses a different definition of *sponsor*, an explanatory footnote is provided.

[3] *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.

[4] For purposes of this guidance, the term *OTC monograph drug* is consistent with the definition at section 744L(5) established for user fee purposes.

[5] Section 505G of the FD&C Act was added by the Coronavirus Aid, Relief, and Economic Security Act (CARES Act), Public Law 116-136, which was enacted on March 27, 2020.

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

[7] See section 505G(h) of the FD&C Act.

procedures to facilitate efficient participation in joint meetings by multiple meeting requesters and/or organizations nominated by them to represent their interests.[8]

For the purposes of this guidance, a *formal meeting* includes a meeting that is requested by a meeting requester following the procedures provided in this guidance and includes meetings conducted in any format (i.e., face to face, teleconference/videoconference, or written response only (WRO)).

This guidance discusses the principles of good meeting management practices and describes standardized procedures for requesting, preparing, scheduling, conducting, and documenting such formal meetings.

This guidance does not apply to meetings for the development of nonprescription drug products intended for submission in new drug applications or abbreviated new drug applications under section 505 of the FD&C Act. This guidance does not apply to meetings between FDA and pre-investigational new drug or investigational new drug sponsors.[9,10]

The contents of this document do not have the force and effect of law and are not meant to bind the public in any way, unless specifically incorporated into a contract. This document is intended only to provide clarity to the public regarding existing requirements under the law. FDA guidance documents, including this guidance, 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.

II. BACKGROUND

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 new drug applications approved 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.

Section 505G(h) of the FD&C Act requires that FDA establish procedures under which meeting requesters can meet with appropriate FDA officials to obtain advice on the studies and other

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

[9] *Sponsor*, in the context of investigational new drug applications, is defined in 21 CFR 312.3.

[10] See the guidance for industry and review staff *Best Practices for Communication Between IND Sponsors and FDA During Drug Development* (December 2017). 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.

information necessary to support submissions under section 505G of the FD&C Act, other matters relevant to the regulation of nonprescription drugs, and the development of new nonprescription drugs under section 505G of the FD&C Act.[11] In addition, section 505G(i) of the FD&C Act requires FDA to, among other things, establish procedures to facilitate efficient participation in joint meetings by multiple meeting requesters and/or organizations nominated by them to represent their interests.[12] Finally, section 505G(l)(1) requires FDA to issue guidance that specifies the procedures and principles for formal meetings between FDA and meeting requesters for OTC monograph drugs.[13] This guidance fulfills all three of these requirements with respect to meetings.

We expect that each year FDA review staff will participate in meetings with meeting requesters who seek advice relating to the development and regulation of OTC monograph drugs. Because these meetings can represent critical points in the regulatory and development process, it is important that there are efficient, consistent procedures for the timely and effective conduct of such meetings. The good meeting management practices described in this guidance are intended to provide consistent procedures that will promote well-managed meetings and to ensure that such meetings are scheduled within a reasonable time, conducted efficiently, and documented appropriately.

The Over-the-Counter Monograph User Fee Program Performance Goals and Procedures document,[14] commonly referred to as the OMUFA commitment letter, specifies FDA and industry mutually agreed-upon timelines for various OTC monograph drug activities. FDA has committed to specific performance goals that include meeting management goals for formal meetings that occur between FDA and meeting requesters. These and other agreed-upon performance goals are described individually throughout this guidance.

III. MEETING TYPES

There are three types of formal meetings that may occur between meeting requesters and FDA staff to obtain advice on the studies and other information necessary to support OTC monograph order submissions, to obtain advice on other matters relevant to OTC monograph drug regulation, or to obtain advice on OTC monograph drug development: Type X, Type Y, and Type Z.

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

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

[13] See section 505G(l)(1) of the FD&C Act.

[14] The meeting types and goal dates are described in the Over-the-Counter Monograph User Fee Program Performance Goals and Procedures document and apply to formal meetings between FDA staff and meeting requesters. The document can be accessed at https://www.fda.gov/media/106407/download. Based on passage of the CARES Act, FDA updated goal dates for fiscal years 2021–2025. That document can be accessed at https://www.fda.gov/media/146283/download.

A. Type X Meeting

Type X meetings are as follows:

- A meeting that is necessary for an otherwise stalled OTC monograph order development program to proceed. For example, a meeting that is requested by a meeting requester within 3 months of FDA's issuing a refuse-to-file letter for an OTC monograph order request (OMOR)[15] submitted by that meeting requester.

- A meeting that is necessary to address an important safety issue that needs immediate action when the meeting requester learns about a safety issue related to an OTC monograph drug that is marketed or being developed.

Before submitting a request for a Type X meeting, meeting requesters should contact FDA to discuss the appropriateness of the request.

B. Type Y Meeting

A Type Y meeting is a meeting intended for milestone discussions during the course of a meeting requester's OTC monograph order development program. Type Y meetings are as follows:

- Overall Data Recommendations Meetings

  A meeting requester may request a meeting to discuss the overall data recommended to support the following:

  - A positive general recognition of safety and effectiveness (GRASE) determination for an OTC monograph drug containing a particular active ingredient or subject to some other condition of use after FDA has stated its intent to make that final GRASE determination

  - An OMOR submission when a meeting requester has an interest in initiating an OMOR (i.e., meeting requester has not yet begun an OTC monograph order development program)

- Pre-OMOR Submission Meeting

  When nearing completion of its development program for an OMOR, a meeting requester should request a pre-OMOR submission meeting to present a summary of the data supporting the OMOR and take the following steps:

[15] *OTC monograph order request* (OMOR) is defined for user fee purposes in section 744L(7) of the FD&C Act and refers to a request for FDA to issue an administrative order under section 505G(b)(5) of the FD&C Act. This term has the same meaning when used in this guidance document.

- Discuss the proposed format for the OMOR

- Obtain FDA feedback on the adequacy of the proposal for the OMOR submission,[16] such as the format and content of the anticipated OMOR, including presentation of data, structure of dataset, acceptability of data for submission, as well as the projected submission date of the OMOR

- Discuss the appropriate categorization of an OMOR (e.g., Tier 1 or Tier 2[17])

The meeting should be held sufficiently in advance of the planned submission of the OMOR to allow for meaningful response to FDA feedback and should generally occur not less than 3 months before the planned submission of the OMOR.

C. Type Z Meeting

A Type Z meeting is any meeting that is not a Type X or Type Y meeting.

IV. MEETING FORMATS

There are three meeting formats: face to face, teleconference/videoconference, and WRO as follows:

- **Face to face** — Traditional face-to-face meetings are those in which the majority of attendees participate in person at FDA.

- **Teleconference/videoconference** — Teleconferences/videoconferences are meetings in which the attendees participate from various remote locations via an audio (e.g., telephone) and/or video connection.

- **WRO** — WRO responses are sent to meeting requesters in lieu of meetings conducted in one of the other two formats described above.

[16] See *generally* section 505G(b)(5)-(6) of the FD&C Act.

[17] The FD&C Act establishes two types of OMORs for user fee purposes: Tier 1 and Tier 2. As described in section 744L(8) of the FD&C Act, a Tier 1 OMOR is any OMOR not determined to be a Tier 2 OMOR. As described in section 744L(9)(A) of the FD&C Act, a Tier 2 OMOR is a request for reordering of existing information in the drug facts label of an OTC monograph drug; addition of information to the "Other Information" section of the drug facts label of an OTC monograph drug (subject to certain limitations); modification to the "Directions for Use" section of the drug facts label of an OTC monograph drug, consistent with a minor dosage form change made pursuant to section 505G(c)(3)(A); standardization of the concentration or dose of a specific finalized ingredient within a particular finalized monograph; change to ingredient nomenclature to align with nomenclature of a standards-setting organization; or addition of an interchangeable term in accordance with 21 CFR 330.1 (or any successor regulations). FDA may also characterize any OMOR as a Tier 2 OMOR as described at section 744L(9)(B).

V. MEETING REQUESTS

To make the most efficient use of FDA resources, meeting requesters should consult the information publicly available from FDA before seeking a meeting. To disseminate a broad range of information in a manner that can be easily and rapidly accessed by interested parties, FDA develops and maintains web pages, portals, and databases and participates in interactive media as a means of providing advice on scientific and regulatory issues that fall outside of established guidance, policy, and procedures.

To promote efficient meeting management, meeting requesters should try to anticipate future needs and, to the extent practical, combine related OTC monograph order development program issues into the fewest possible meetings.

To request a meeting, meeting requesters must submit a written request to FDA electronically.[18]

The meeting request should include adequate information for FDA to assess the potential utility of the meeting and to identify FDA staff necessary to discuss proposed agenda items.

The meeting request should include the following information:

1. The OMOR number, if applicable.

2. The product name, if applicable.

3. The relevant OTC monograph, or if an OTC monograph has not yet been established, the proposed therapeutic category.

4. The chemical name, established name, and/or structure.

5. Indications or proposed indications (uses).

6. The meeting type being requested (i.e., Type X, Type Y, or Type Z) and the rationale for requesting the meeting type.

7. Suggested dates and times (e.g., morning or afternoon) for the meeting that are within or beyond the appropriate scheduling time frame of the meeting type being requested (see Table 2 in section VI.A, Meeting Granted). Dates and times when the meeting requester is not available should also be included.

8. A list of questions, grouped by FDA discipline. For each question there should be a brief explanation of the context and purpose of the question.

[18] See section 505G(j) of the FD&C Act.

The meeting request must include the following information to qualify for OMUFA performance goals:[19]

1. A brief statement of the purpose of the meeting. This statement should include a brief background of the issues underlying the agenda. It can also include a brief summary of data that the meeting requester intends to discuss at the meeting, the general nature of the critical questions to be asked, and where the meeting fits in the overall OTC monograph order development program. Although the statement should not provide the details of studies and clinical trials, it should provide enough information to facilitate understanding the issues, such as a small table that summarizes major results.

2. The proposed format of the meeting (i.e., face to face, teleconference/videoconference, or WRO).

3. A listing of the specific objectives or outcomes the meeting requester expects from the meeting.

4. A proposed agenda, including estimated times needed for discussion of each agenda item.

5. A statement of whether the meeting requester intends to discuss information exempt from disclosure under section 505G(d) of the FD&C Act or other laws at the meeting.

6. A list of planned attendees from the meeting requester's organization, which should include their names and titles. The list should also include the names, titles, and affiliations of consultants and interpreters, if applicable.

7. A list of requested attendees and/or discipline representatives from the Center for Drug Evaluation and Research (CDER) with an explanation for the request as appropriate. Requests for attendance by FDA staff who are not otherwise essential to the meeting discussion may affect the ability to hold the meeting within the specified time frame of the meeting type being requested. Therefore, when attendance by nonessential FDA staff is requested, the meeting request should provide a justification for such attendees and state whether a later meeting date is acceptable to the meeting requester to accommodate the nonessential FDA attendees.

8. The date that the meeting package will be sent to FDA by the meeting requester (see section VII.A., Timing of Meeting Package Submission). Meeting packages should be included with the meeting request for all Type X meetings.

When submitting a meeting request, the meeting requester should define the specific areas of input needed by FDA. A well-written meeting request that includes the above components can help FDA understand and assess the utility and timing of the meeting. The list of meeting

[19] The meeting types and goal dates are described in the *Over-the-Counter Monograph User Fee Program Performance Goals and Procedures* document and apply to formal meetings between FDA staff and requesters of OTC monograph meetings. The document can be accessed at https://www.fda.gov/media/106407/download.

requester attendees and the list of requested FDA attendees can be useful in providing or preparing for the input needed at the meeting. However, during the time between request and meeting, the planned attendees can change. If there are changes, an updated list of attendees with their titles and affiliations should be provided to the appropriate FDA contact before the meeting.

The objectives and agenda provide overall context for the meeting topics, but it is the list of questions that is the most critical to understanding the kind of information or input needed by the meeting requester and to focus the discussion should the meeting be granted. Each question should be precise and include a brief explanation of the context and purpose of the question. The questions submitted within a single meeting request should be limited to those that can be reasonably answered within the allotted meeting time, taking into consideration the complexity of the questions submitted. Similar considerations regarding the complexity of the questions submitted within a WRO should be applied.

VI. ASSESSING AND RESPONDING TO MEETING REQUESTS

The meeting requester can request a specific meeting type and format. For any type of meeting, the meeting requester may request a WRO rather than a face-to-face meeting or teleconference. FDA assesses each meeting request, including WRO requests, and determines whether the request should be granted, the appropriate meeting type, and the appropriate meeting format. FDA may determine that a WRO is the most appropriate means for providing feedback and advice for the meeting. When it is determined that the meeting request can be appropriately addressed through a WRO, FDA will notify the meeting requester in FDA's response to the meeting request, as described in section VI.A., Meeting Granted.

Requests for Type Y meetings will be honored except in unusual circumstances. Generally, FDA will not grant a meeting requester more than one Type Y meeting to discuss a particular OTC monograph order development program or conditions of use for a particular OTC monograph.

A. Meeting Granted

If a meeting request is granted, FDA will notify the meeting requester in writing according to the timelines described in Table 1. For face-to-face and teleconference/videoconference meetings, the notification will include the date, time, conferencing arrangements and/or location of the meeting, and expected FDA participants. For WRO meetings, the notification will include the date FDA intends to send the written response. WRO response timelines are the same as those for scheduling face-to-face and teleconference/videoconference meetings.

For face-to-face and teleconference/videoconference meetings, FDA will schedule the meeting on the next available date at which all expected FDA staff are available to attend; however, the meeting should be scheduled consistent with the type of meeting requested (see Table 2 for FDA meeting scheduling time frames). If the requested date for any meeting type is later than the

specified FDA meeting schedule time frame, the meeting date should be within 14 calendar days of the requested date.

Table 1: Meeting Request Response Time Goals	
Meeting Type	**FDA's Response Time (calendar days from receipt of meeting request/WRO request)**
X	14
Y	14
Z	21

Table 2: Meeting Scheduling or WRO Times	
Meeting Type	**Meeting Scheduling or WRO Time (calendar days from receipt of request)**
X	30 calendar days from receipt of meeting request
Y	70 calendar days from receipt of meeting request
Z	75 calendar days from receipt of meeting request

B. Meeting Denied

If a meeting request is denied, FDA will notify the meeting requester in writing according to the timelines described in Table 1. The notification will include an explanation of the reason for the denial. Denials will be based on a substantive reason, not merely on the absence of a minor element of the meeting request or minor element of the meeting package. For example, a meeting request may be denied because it is clearly unnecessary; the meeting package does not provide an adequate basis for the meeting discussion; in situations when FDA recommends submission of a meeting package at the time of the request, the meeting package is either not included in the original request or does not provide an adequate basis for the meeting discussion (e.g., Type X meeting requests); or the meeting would be duplicative of a prior meeting.

FDA may also deny requests for meetings that do not have the substantive information related to the elements described in section V., Meeting Requests. A subsequent request to schedule the meeting will be considered as a new request (i.e., a request that is assigned a new set of timelines described in section VI.A., Meeting Granted).

FDA will deny a meeting request for an OTC monograph drug meeting[20] from a person subject to fees under section 744M of the FD&C Act, including an OTC monograph drug meeting request from an affiliate, until all such fees owed by such person have been paid.[21]

VII. MEETING PACKAGE

Premeeting preparation is critical for achieving a productive discussion or exchange of information. Preparing the meeting package should help the meeting requester focus on describing its principal areas of interest. The meeting package should provide information relevant to the discussion topics and enable FDA to prepare adequately for the meeting. In addition, the timely submission of the meeting package is important for ensuring that there is enough time for meeting preparation, accommodation of adjustments to the meeting agenda, and accommodation of appropriate preliminary responses to meeting questions.

A. Timing of Meeting Package Submission

The meeting requester should submit the meeting package to FDA for each meeting type (including WRO) no later than the date specified in Table 3.

Table 3: Meeting Requester Meeting Package Timelines

Meeting Type	FDA Receipt of Background Package (calendar days)
X	At the time of the meeting request
Y	No later than 50 calendar days before the date of the meeting or expected written response time
Z	No later than 47 calendar days before the date of the meeting or expected written response time

[20] An *OTC monograph drug meeting* is defined in section 744L(11) of the FD&C Act for user fee purposes as any meeting regarding the content of a proposed OMOR.

[21] See section 744M(e) FD&C Act.

B. Where and How Many Copies of Meetings Packages to Send

The meeting package must be submitted electronically to FDA.[22]

To facilitate the meeting process, an FDA regulatory project manager (RPM) may request that copies of meeting packages provided in electronic format also be provided in paper (desk copies) and sent to the FDA RPM at the mailing address provided in the letter granting the meeting.

C. Meeting Package Content

The meeting package should identify the subject of the meeting and the date and time of the meeting, if known. The meeting package should provide *summary* information relevant to the OTC monograph order development program or the regulation of the OTC monograph drug and any supplementary information needed to develop responses to issues raised by the meeting requester or the review division. It is critical that the entire meeting package content support the intended meeting objectives. The meeting package content will vary depending on the type and subject of the meeting. FDA and ICH guidances identify and address many issues related to drug development and should be considered when planning, developing, and providing information needed to support a meeting with FDA. If an OTC monograph order development program deviates from current guidances, or from current practices, the deviation should be recognized and explained. Known difficult design and evidence issues should be raised for discussion.

To facilitate FDA review, the meeting package content should be organized according to the proposed agenda. The meeting package should be a sequentially paginated document with a table of contents, appropriate indices, appendices, and cross references. It should be tabbed or bookmarked to enhance reviewers' navigation across different sections within the package, both in preparation for and during the meeting. Meeting packages generally should include the following information, preferably in the order listed below:

1. The OMOR number, if previously assigned.

2. The product name, if applicable.

3. The relevant OTC monograph, or if a relevant OTC monograph has not yet been established, the relevant therapeutic category.

4. Chemical name, established name, and/or structure.

5. United States Pharmacopeia active ingredient monograph, if applicable.

6. The indications or proposed indications (uses) or context of OTC monograph order development program.

[22] See section 505G(j) of the FD&C Act.

7. The proposed tier of the OMOR (Tier 1 or Tier 2),[23] if applicable.

8. Dosage form, route of administration, and dosing regimen (strength, frequency, and duration), if applicable.

9. A list of all individuals, with their titles and affiliations, who will attend the requested meeting from the meeting requester's organization, including consultants and interpreters. FDA, in general, expects non-FDA attendees will be limited to those listed in the meeting package and expects to be notified in advance of any changes to the list of attendees.

10. A background section that includes the following:

    a. A brief history and information about the issues to be discussed at the meeting about the OTC monograph order development program, regulation of the OTC monograph drug, or OTC monograph drug development, including substantive changes in development plans and current status of development, and relevant communications with FDA before the meeting.

    b. If applicable, a list of completed, ongoing, and planned studies.

11. A brief statement summarizing the purpose of the meeting.

12. A proposed agenda, including estimated times needed for discussion of each agenda item.

13. A list of the final questions for discussion grouped by discipline and with a brief summary for each question to explain the need or context for each question. In general, there should be no more than 10 questions listed consecutively regardless of discipline. For example, if Question 1 has three parts, the numbering should be 1, 2, and 3 rather than numbering them 1a, 1b, and 1c. If there are three clinical questions and three nonclinical questions, for a total of six questions, each question should have its own number (i.e., 1, 2, 3, 4, 5, 6, not Clinical 1, 2, 3 and then Nonclinical 1, 2, 3). The numbering of each question in the meeting request (see section VI, Assessing and Responding to Meeting Requests) should be identical to the numbering of each question in the meeting package. FDA requests that meeting requesters not submit subquestions.

14. Data to support discussion, organized by FDA discipline and question. The level of detail of the data should be appropriate to the meeting type requested. Protocols, full study and trial reports, or detailed data generally are not appropriate for meeting packages; the summarized material should describe the results of relevant studies and clinical trials with some degree of quantification and any decision about clinical trials that resulted. If applicable, the trial endpoints should be stated, as should whether endpoints were altered or analyses changed during the trial.

[23] See section 744L(8) and (9) of the FD&C Act.

VIII. PRELIMINARY RESPONSES

Communications before the meeting between meeting requesters and FDA, including preliminary responses, can serve as a foundation for discussion or as the meeting's final responses. Nevertheless, preliminary responses should not be construed as *final* unless there is agreement between the meeting requester and FDA that additional discussion is not necessary for any question (i.e., when the meeting is canceled because the meeting requester is satisfied with the FDA's preliminary responses) or a particular question is considered resolved allowing extra time for discussion of the other questions during the meeting. Preliminary responses communicated by FDA are not intended to generate the submission of new information or new questions. If a meeting requester nonetheless provides new data or a revised or new proposal, FDA may not be able to provide comments on the new information, and the meeting requester may need to submit a new meeting request for FDA to provide feedback on the new information.

FDA holds internal meetings to discuss the content of meeting packages and to compose and gain internal alignment on the preliminary responses. FDA will send the meeting requester its preliminary responses to the questions in the meeting package no later than 5 calendar days before the meeting date for Type Y and Type Z meetings. FDA will generally not send preliminary responses for Type X meetings. For Type Y and Type Z meetings, the meeting requester should notify FDA no later than 3 calendar days following receipt of FDA's preliminary responses regarding whether the meeting is still needed. If the meeting requester believes the meeting is still needed after receipt of FDA's preliminary responses, the meeting requester should send FDA a revised meeting agenda indicating which questions the meeting requester considers resolved and which questions the meeting requester will want to further discuss.

IX. RESCHEDULING MEETINGS

Occasionally, circumstances arise that necessitate the rescheduling of a meeting. If a meeting needs to be rescheduled, it should be rescheduled as soon as possible after the original date. A new meeting request should not be submitted. Meeting requesters and FDA should take reasonable steps to avoid rescheduling meetings. For example, if an attendee becomes unavailable, a substitute can be identified, or comments on the topic that the attendee would have addressed can be forwarded to the requester following the meeting. It will be at the discretion of the review division whether the meeting should be rescheduled depending on the specific circumstances.

The following situations are examples of when a meeting may be rescheduled by FDA. This list includes representative examples and is not intended to be an exhaustive list.

- The meeting requester experiences a minor delay in submitting the meeting package. The requester should contact FDA to explain why the timelines for submission will be missed and when the meeting package will be submitted.

- The review team determines that the meeting package is inadequate or additional information is needed to address the meeting requester's questions or other important issues for discussion and it is possible to identify the additional information needed and arrange for its timely submission.

- There is insufficient time to review the material because the meeting package is voluminous (see section VII.C., Meeting Package Content) despite submission within the specified timelines and the appropriateness of the content.

- After the meeting package is submitted, the meeting requester sends FDA additional questions or data that are intended for discussion at the meeting and require additional review time.

- The meeting package contains additional questions or significant changes to questions from those submitted with the meeting request.

- It is determined that attendance by additional FDA personnel not originally anticipated or requested are critical and their unavailability precludes holding the meeting on the original date.

- Essential attendees are no longer available for the scheduled date and time because of an unexpected or unavoidable conflict or an emergency situation.

X. CANCELING MEETINGS

Failure to pay required fees will result in FDA canceling a previously scheduled meeting.[24] If the meeting requester pays the required fee or fees after the meeting has been canceled because of nonpayment, FDA will consider a subsequent request to schedule a meeting to be a new request and the goal timeline for FDA's response will be calculated from the date of the subsequent request.

Occasionally, other circumstances arise that necessitate the cancellation of a meeting.

The following situations are examples of when a meeting can be canceled. This list includes representative examples and is not intended to be an exhaustive list.

- The meeting package is not received by FDA within the specified timelines (section VII.A., Timing of Meeting Package Submission).

- FDA determines that the meeting package is inadequate. Meetings are scheduled on the assumption that the meeting requester has submitted appropriate information to support the discussion. Adequate planning by the meeting requester should avoid this problem.

[24] See section 744M(e)(3) of the FD&C Act.

- The meeting package and questions are substantively different from the original request and no longer meet the criteria for the meeting granted (see section VI., Assessing and Responding to Meeting Requests).

- The meeting requester determines that preliminary responses to its questions are sufficient for its needs and additional discussion is not necessary (see section VIII., Preliminary Responses). In this case, the meeting requester should contact the FDA RPM to request cancellation of the meeting. FDA will consider whether it agrees that the meeting should be canceled. Some meetings can be valuable because of the discussion they generate and the opportunity for the division to ask about relevant matters, even if the preliminary responses seem sufficient to answer the meeting requester's questions. If FDA agrees that the meeting can be canceled, the reason for cancellation will be documented and the preliminary responses will represent the final responses and the official record.

If a circumstance arises that necessitate the cancellation of a meeting, FDA will consider a subsequent request to schedule a meeting to be a new request and the goal timeline for FDA's response will be calculated from the date of the subsequent request. Meeting requesters and FDA should take reasonable steps to avoid canceling meetings (unless the meeting is no longer necessary). Cancellation will be at the discretion of the review division and will depend on the specific circumstances.

XI. MEETING CONDUCT

Meetings will be chaired by an FDA staff member and begin with introductions and an overview of the agenda. Attendees should not make audio or visual recordings of discussions at meetings described in this guidance. All parties to a meeting are expected to behave in a professional manner. If attendees are not behaving professionally during the meeting, FDA reserves the right to end the meeting immediately.

Presentations by meeting requesters generally are not needed because the information necessary for review and discussion should be part of the meeting package. If a meeting requester plans to make a presentation, the presentation should be discussed ahead of time with the FDA RPM to determine if a presentation is warranted and ensure that FDA has the presentation materials ahead of the meeting, if possible. All presentations should be kept brief to maximize the time available for discussion. The length of the meeting will not be increased to accommodate a presentation. If a presentation contains more than a small amount of content distinct from clarifications or explanations of previous data and the content was not included in the original meeting package submitted to FDA for review, FDA staff may not be able to provide commentary.

Either a representative of FDA or the meeting requester should summarize the important discussion points, agreements, clarifications, and action items. Summation can be done at the end of the meeting or after the discussion of each question. Generally, the meeting requester will be asked to present the summary to ensure that there is mutual understanding of meeting

outcomes and action items. FDA staff can add or further clarify any important points not covered in the summary, and these items can be added to the meeting minutes.

XII. MEETING MINUTES

Because FDA's minutes are the official records of meetings, FDA's documentation of meeting outcomes, agreements, disagreements, and action items is critical to ensuring that this information is preserved for meeting attendees and future reference. FDA intends to issue the official, finalized minutes to the meeting requester within 30 calendar days after the meeting. Meeting minutes will not be taken if FDA transmits a WRO for any meeting type.

The following are general considerations regarding meeting minutes:

- FDA minutes will outline the important agreements, disagreements, issues for further discussion, and action items from the meeting in bulleted format. This information need only be sufficient in detail to ensure clarity on the discussion and action items from the meeting. The minutes are not intended to represent a transcript of the meeting.

- FDA RPMs will use established templates to ensure that all important meeting information is captured.

- FDA may communicate additional information in the final minutes that was not explicitly communicated during the meeting or that provides further explanation of discussion topics. FDA's final minutes will distinguish this additional information from the discussion that occurred during the meeting.

The following steps should be taken when there is a difference of understanding regarding the minutes:

- The meeting requester should contact the FDA RPM if there is a significant difference in their understanding and FDA's understanding of the content of the final meeting minutes issued to the meeting requesters.

- If after contacting the FDA RPM there are still significant differences in the meeting requester's understanding and FDA's understanding of the content of the official meeting minutes, the meeting requester should submit a description of the specific disagreements in a letter to the division director, with a copy to the FDA RPM.

- The review division and the office director, if the office director was present at the meeting, will take the meeting requester's concerns under consideration.

  - If the minutes are deemed to reflect the meeting discussion accurately and sufficiently, the FDA RPM will convey this decision to the meeting requester and the minutes will stand as the official documentation of the meeting.

- If FDA deems it necessary, changes will be documented in an addendum to the official minutes.

For input on additional issues that were not addressed at the meeting, the meeting requester should submit a new meeting request.

XIII. FORMAL MEETINGS WITH MULTIPLE MEETING REQUESTERS (JOINT MEETINGS)

A. General Information About Joint Meetings

Multiple meeting requesters may want to join together and have a formal meeting with FDA to discuss studies and other information necessary to support OTC monograph order submissions, matters relevant to the regulation of OTC monograph drugs, or OTC monograph drug development that the multiple meeting requesters have a common interest in. These formal meetings with multiple meeting requesters are known as joint meetings.

A joint meeting may be requested for Type X, Type Y, and Type Z meetings.

For example, joint meeting requests may be appropriate for the following:

- A Type Y meeting to discuss overall data requested to support a positive GRASE determination after FDA has stated its intent to make a final GRASE determination for a particular monograph ingredient or other monograph condition of use

- A Type X meeting to discuss safety concerns with a marketed OTC monograph drug

Because of facility and space limitations for face-to-face meetings, the number of individuals able to attend the joint meeting in person may be limited. The FDA RPM will inform the meeting requesters of the total number of individuals who can attend in person when the meeting is granted.

To the extent that information submitted to FDA for discussion at the meeting could be protected from disclosure under section 505G(d) of the FD&C Act or other laws (see section XIV, Confidentiality of Information Submitted to FDA for Formal Meetings), the meeting request should include authorizations from each of the multiple meeting requesters for FDA to discuss that information with the other meeting requesters participating in the meeting.

B. Formation of an OTC Monograph Industry Working Group

To facilitate efficient participation by multiple meeting requesters, meeting requesters may consider forming an OTC monograph industry working group (OTC IWG) to collaborate on issues of common interest. The OTC IWG may consist of multiple meeting requesters and organizations nominated by meeting requesters to represent their interests. Each member of the OTC IWG should be a meeting requester eligible for formal meetings with FDA or be an

organization nominated by a meeting requester to represent their interests. Members of the OTC IWG who are subject to fees under section 744M of the FD&C Act, including their affiliates, must not have any unpaid user fees to participate in an OTC monograph drug meeting[25]

The OTC IWG should consider creating agreements among its members on matters such as confidentiality, governance, and any other issues that may come up during the collaboration. FDA does not advise on the business arrangements between members of an OTC IWG nor mediate between parties within an OTC IWG.

If an OTC IWG is formed, the OTC IWG should designate a single point of contact (POC) to represent the OTC IWG in communications with FDA. The POC should facilitate all communication between FDA and the OTC IWG about the joint meeting. FDA will communicate only with the POC about the joint meeting. The POC should be responsible for all submissions related to the joint meeting and should be the only individual who submits information to FDA for the joint meeting. FDA should be notified with appropriate documentation if a new POC is designated at any time during the joint meeting process.

FDA will not meet individually with any meeting requester who is a member of an OTC IWG to discuss an issue that is the subject of a joint meeting for which the meeting requester attended or is scheduled to participate in unless the OTC IWG nominates such meeting requester to meet individually with FDA.

C. Procedures for Joint Meetings

1. Meeting Request

The POC can request a joint meeting on behalf of the OTC IWG consistent with section V., Meeting Requests. In addition to the information that should be submitted in the meeting request (see section V., Meeting Requests), the meeting request should include the following information:

- The meeting being requested is a joint meeting
- Appropriate documentation of the formation of the OTC IWG and a list of its members, including organizations nominated by meeting requesters to represent their interests
- The name of the POC as designated by the OTC IWG and appropriate documentation from OTC IWG designating the POC
- Appropriate documentation from a member or members of the OTC IWG nominating an organization to represent its interests, if applicable

[25] An *OTC monograph drug meeting* is defined in section 744L(11) of the FD&C Act for user fee purposes as any meeting regarding the content of a proposed OMOR.

- To the extent that information submitted to FDA for discussion at the meeting could be protected from disclosure under section 505G(d) of the FD&C Act, authorization from each member of the OTC IWG that FDA may disclose that information to the other meeting requesters participating in the meeting

2. Meeting Package

In addition to the information that should be submitted in the meeting package (see section VII. C., Meeting Package Content), the meeting package should include the following information:

- Any specific topics of discussion that should not be discussed because the OTC IWG has not agreed to share information protected from disclosure under section 505G(d) of the FD&C Act or other laws

3. Meeting Conduct

The OTC IWG POC is responsible for ensuring that discussion during the joint meeting is consistent with OTC IWG agreements on confidentiality.

XIV. CONFIDENTIALITY OF INFORMATION SUBMITTED TO FDA IN CONNECTION WITH FORMAL MEETINGS

The OTC monograph order process is generally a public process. Under this order process, section 505G(d) of the FD&C Act limits the information that can be confidentially submitted to FDA in connection with proceedings on an order, including an OMOR. This limitation on confidentiality extends to formal meeting requests and information submitted to FDA in connection with a formal meeting. Such information in the context of formal meetings may include the meeting package, meeting minutes, and other meeting correspondence.

In general, until disclosure is triggered under section 505G(d)(2) of the FD&C Act, any information, including reports of testing conducted on the drug or drugs involved, that is submitted by a requestor in connection with proceedings on an order under section 505G and is a trade secret or confidential information subject to section 552(b)(4) of title 5 of U.S.C. or section 1905 of title 18 of U.S.C. will not be disclosed to the public unless the requestor consents to that disclosure.[26] However, FDA must make any information submitted by a requestor in support of an OMOR (e.g., meeting requests and meeting packages submitted by an OMOR requestor) available to the public not later than the date on which the proposed order is issued.[27] Additionally, FDA must make any information submitted by any other person with respect to an order requested (or initiated by FDA) available to the public upon such submission.[28]

[26] See section 505G(d)(1) of FD&C Act.

[27] See section 505G(d)(2)(A)(i) of FD&C Act.

[28] See section 505G(d)(2)(A)(ii) of FD&C Act.

Nonetheless, in both circumstances, the information 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; (2) the information is of the type contained in raw datasets; (3) the information is submitted in a requestor-initiated request, but the requestor withdraws the request in accordance with withdrawal procedures established by FDA before FDA issues the proposed order; or (4) FDA requests and obtains the information under 505G(c) and the information is not submitted in relation to an order under 505G(b).[29]

In addition, although certain information in connection with a formal meeting may be publicly disclosed or otherwise publicly available in accordance with section 505G(d) of the FD&C Act, a formal meeting is not open to the public to attend and only the meeting requester or, for joint meetings, the group of meeting requesters and/or their representatives may be present at the meeting with FDA.[30]

[29] See section 505G(d)(2)(B) of FD&C Act.

[30] 21 CFR 10.65(c).