OTC Monograph Reform: Overview of Draft Guidance for Industry: Formal Meetings Between FDA and Sponsors or Requestors of Over-the-Counter Monograph Drugs

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Objectives

Draft Guidance for Industry: Formal Meetings Between FDA and Sponsors or Requestors of Over-the-Counter Monograph Drugs

- Provide overview of draft guidance
- Explain OMUFA timelines for meetings

OTC Monograph Reform

- On March 27, 2020, the “Coronavirus Aid, Relief, and Economic Security Act” (CARES Act) was enacted
- Includes important statutory provisions that reform and modernize the way OTC monograph drugs are regulated in the United States
  - Replaces the rulemaking process with an administrative order process to establish, revise, or amend OTC monographs
- Grants FDA the authority to assess and collect fees from regulated industry

Overview of Draft Guidance for Industry: Formal Meetings Between FDA and Sponsors or Requestors of Over-the-Counter Monograph Drugs

Overview of Draft Guidance

FDA issued this guidance to:

- Specify procedures and principles for formal meetings with FDA and sponsors or requestors of OTC monograph drugs (“meeting requesters”).
- Describe procedures under which meeting requesters can meet with appropriate FDA officials to obtain advice on:
  - Studies or other information necessary to support a submission under section 505G of the FD&C Act
  - Matters relevant to the regulation of OTC monograph drugs
  - Development of new OTC monograph drugs
- Specify procedures to facilitate efficient participation by multiple sponsors or requestors and/or organizations nominated by them to represent their interests

Draft Guidance Performance Goals

Over-the-Counter Monograph User Fee Program Performance Goals and Procedures (commonly referred to as OMUFA commitment letter)

- FDA agreed to meeting management goals for formal meetings (OMUFA performance goals)
- FDA also committed to issuing this guidance under specific timelines

Who Can Request a Formal Meeting?

Formal meetings are between FDA and sponsors and requestors of OTC monograph drugs (referred to collectively as meeting requesters)

- **Sponsor:** 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 505G
- **Requestor:** any person or group of persons marketing, manufacturing, processing, or developing a drug

Meeting Types Overview

Type X	Type Y	Type Z
• Necessary for an otherwise stalled OTC monograph order development program to proceed • Important safety issue that needs immediate action	• Overall data recommendations • Pre-OTC monograph Order Request (OMOR) submission	Any meeting that is not a Type X or Type Y meeting

Meeting Types

Type X

- Necessary for an otherwise stalled OTC monograph order development program to proceed
  - For example, a meeting within 3 months of FDA issuing a refuse-to-file letter for an OMOR
- 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

Meeting Types (cont'd)

Type Y

Milestone discussions during the course of the meeting requester's OTC monograph order development program

- Overall data recommendations 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)

Meeting Types (cont'd)

Type Y (cont'd)

- Pre-OMOR Submission:
  - May request when nearing completion of the development program for an OMOR to:
    - Present a summary of the data supporting the OMOR
    - Discuss the proposed format for the OMOR
    - Obtain FDA feedback on the adequacy of the proposal for the OMOR submission
    - Discuss the appropriate categorization of an OMOR (e.g., Tier 1 or Tier 2)

Meeting Types (cont'd)

Type Z

- Any meeting that is not a Type X or Type Y meeting

Meeting Formats

Face-to-Face

Teleconference or Videoconference

Written Response Only (WRO)

Meeting Request: Submission

- A meeting request must be submitted to FDA electronically
- Guidance on how to submit OTC monograph submissions electronically is forthcoming
- Prior to publication of that guidance, email meeting requests to: Monograph-Meeting-Requests@fda.hhs.gov

Meeting Request: Content

A 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

- Draft guidance specifies information that should be included in the request
- Draft guidance specifies information that must be included qualify for OMUFA performance goals

Meeting Request: Content (cont'd)

To qualify for OMUFA performance goals, a written meeting request **must** include:

- Brief statement of the purpose of the meeting
- Proposed format of the meeting
- List of specific objectives or outcomes
- Proposed agenda, including estimated time needed for discussion of each agenda item
- 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
- List of meeting requester's planned attendees, including their names and titles
- List of requested CDER attendees and/or disciplines, including an explanation for the request as appropriate
- Date that the meeting package will be sent to FDA

Assessing Meeting Request

FDA assesses each meeting request and determines:

- whether the request should be granted or denied
- the appropriate meeting type
- the appropriate meeting format

Meeting Granted 

FDA will provide written notification

- For face-to-face or teleconference meetings, the notification includes:
  - Date/time
  - Conference arrangements or location
  - Expected FDA participants
- For WRO, the notification includes the date FDA intends to send the written response

Meeting Request Response Time Goals

Meeting Type	FDA's Response Time (calendar days from receipt of request)
X	14
Y	14
Z	21

Meeting Scheduling or WRO Times

Meeting Type	Meeting Scheduling or WRO Time (calendar days from receipt of request)
X	30
Y	70
Z	75

Meeting Denied 

- FDA will provide written notification with explanation of the reason for the denial
- Reasons for denials include:
  - A substantive reason (not merely the absence of a minor element of the meeting request or meeting package items)
  - Failure to pay fees
- A subsequent request to schedule the meeting will be considered a new request

Meeting Package

- Should provide information relevant to the discussion topics
- Should enable FDA to prepare adequately for the meeting
- Must submit electronically to FDA

Timing of Meeting Package

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

Preliminary Responses

- Communication from FDA prior to the meeting that serves as a foundation for discussion
- Not a final response unless there is agreement between meeting requester and FDA that:
  - additional discussion is not necessary for any question
  - a particular question is considered resolved allowing extra time for discussion of the other questions during the meeting
- Not intended to generate submission of new information or questions

Preliminary Responses (cont'd)

Meeting Type	Preliminary Responses (NOT later than X days before meeting)
X	N/A
Y	5 days
Z	5 days

Meeting requester should follow up with FDA notifying whether meeting still needed or revised agenda

Rescheduling Meetings

- FDA has the discretion to reschedule meetings
- A new meeting request should not be submitted
- Examples of situations when a meeting may be rescheduled:
  - Minor delays in submitting meeting package
  - Meeting package inadequate or more information needed
  - Meeting package contains additional questions or significant changes to questions from those submitted in the meeting request

Canceling Meetings

- FDA has the discretion to cancel meetings
- Examples of circumstances that necessitate the cancellation of a meeting
  - Failure to pay required fees
  - Other situations
    - Meeting package not received within specified timeframe
    - Meeting package inadequate
    - Meeting package and questions are different from the original request and no longer meet criteria for meeting granted
    - Meeting requester determines preliminary responses are sufficient

Meeting Conduct

- Meetings will be chaired by an FDA staff member
- Attendees should not make audio or visual recordings of meeting discussions
- Presentations by meeting requesters are generally not needed
- Generally, the meeting requester will be asked to summarize the meeting

Meeting Minutes

- Official record of the meeting
  - Documents meeting outcomes, agreements, disagreements, and action items
  - May communicate additional information not explicitly communicated during meeting or that provides further explanation of discussion topics
- Generally issued within 30 calendar days after the meeting (except WRO)

JOINT MEETINGS

Joint Meetings

- Formal meetings with multiple meeting requesters
- All meeting types (X, Y, and Z)

OTC Monograph Industry Working Group (OTC IWG)

- Meeting requesters may consider forming OTC IWG to collaborate on issues of common interest
- Members
  - Should be meeting requesters eligible for formal meetings or an organization nominated by a meeting requester to represent their interests
  - must not have unpaid user fees in order to participate in an OTC monograph drug meeting as defined at FD&C Act s. 744L(11)
- Agreements
  - Consider creating agreements among OTC IWG members on matters such as confidentiality, governance, and any other issues
- Point of contact (POC)
  - Should designate a POC to communicate with FDA
  - FDA will not discuss an issue that is the subject of a joint meeting with an individual requester

Joint Meetings: Meeting Requests

A meeting request for a joint meeting should include:

- All information that should be included for a meeting request by a single meeting requester
- Meeting is a joint meeting
- Documentation of the formation of the OTC IWG and a list of its members
- Name of the POC and appropriate documentation from the OTC IWG designating the POC
- Appropriate documentation from a member or members of the OTC IWG nominating an organization to represent its interests
- Request submitted by the POC on behalf of the OTC IWG
- To the extent that information submitted to FDA for discussion at the meeting could be protected from disclosure under s. 505G(d), authorization from each of the multiple meeting requesters for FDA to discuss that information with the other meeting requesters participating in the meeting

Joint Meetings: Meeting Package

Joint meeting package should include:

- All information recommended for meeting package by a single meeting requester
- Any specific discussion topics that should not be discussed because OTC IWG has not agreed to share information protected from disclosure

Joint Meetings: Meeting Conduct

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

- 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

CONFIDENTIALITY

Confidentiality

- OTC monograph order process is generally a public process
- Section 505G(d) limits information that can be confidentially submitted to FDA in connection with proceedings on an order, including formal meeting requests and information submitted to FDA in connection with a formal meeting
- Although certain information in connection with a formal meeting may be disclosed or otherwise publicly available in accordance with 505G(d) of the FD&C Act, a formal meeting is not open to the public to attend

Public Comment

- FDA posted the draft guidance on February 1, 2022
- Notice of Availability (NOA) was published in the *Federal Register on February 7, 2022* (87 FR 6877)
  - NOA provides instructions for submitting comments
- To ensure FDA considers your comment before it begins work on the final guidance, submit by April 8, 2022

Resources

- **OTC Monograph Reform in the CARES Act**
  https://www.fda.gov/drugs/over-counter-otc-nonprescription-drugs/over-counter-otc-drug-review-otc-monograph-reform-cares-act#omor

- **OTC Monograph Database**
  https://www.accessdata.fda.gov/scripts/cder/omuf/index.cfm

- **Over-the-Counter OTC/Nonprescription Drugs**
  https://www.fda.gov/drugs/how-drugs-are-developed-and-approved/over-counter-otc-nonprescription-drugs

- **Draft Meeting Guidance**
  https://www.fda.gov/regulatory-information/search-fda-guidance-documents/formal-meetings-between-food-and-drug-administration-and-sponsors-or-requestors-over-counter

Contact Us

- For questions on the *Formal Meetings Between FDA and Sponsors or Requestors of Over-the-Counter Monograph Drugs* draft guidance, email FDA at druginfo@fda.hhs.gov

- Additional Questions:
  - OTC Monograph Reform druginfo@fda.hhs.gov
  - User fees (OMUFA) CDERCollections@fda.hhs.gov
  - Meeting requests monograph-meeting-requests@fda.hhs.gov
  - Small business and industry assistance cdersbia@fda.hhs.gov

Questions?

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