FDA Formal Meetings: What's New under PDUFA, BsUFA, and OMUFA

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Agenda

- Discuss What's New in Formal Meetings:
  - Prescription Drug User Fee Act (PDUFA VII)
  - Biosimilar User Fee Act (BsUFA III)
- Discuss Meetings under the Over-the-Counter Monograph User Fee Act (OMUFA)
- Provide Update on FDA Formal Meeting Formats
- Provide Meeting Best Practices

PDUFA MEETINGS:
What's New Under PDUFA VII?

PDUFA VII Meeting Changes

- **New Meeting Types**:
  - Type D
  - INitial Targeted Engagement for Regulatory Advice on CBER/CDER ProducTs (INTERACT)
  - Follow-up Opportunity

Type D Meetings

- Narrow set of issues (often one, but typically not more than two issues and associated questions)
- Should not require input from more than 3 disciplines/divisions
- If scope of meeting is too broad or includes complex issues/questions, FDA will inform sponsor that the meeting will be converted to Type B or C

INTERACT Meetings

- Early in development
- Novel, challenging issues (prior to submission of an IND) that otherwise may delay initiation or progress of IND-enabling studies
- Questions and topics include:
  - Novel questions where there is no existing guidance or other written information to reference
  - FDA input on issues that sponsor needs to address prior to pre-IND meeting

Written Follow-up Opportunity

- Questions that arise after receiving FDA minutes/written response
- Clarifying questions only
- FDA will exercise discretion for these requests
- Request for Clarification must be officially submitted to application within 20 calendar days after receipt of minutes/WRO
- FDA will issue response in writing within 20 calendar days

PDUFA Meeting Types and Goal Dates

Meeting Type	Respond Within:	Meeting Scheduled/ WRO Due Within:	Background Package Due:	Preliminary Comments Due:
A	14 days	30 days	At time of request	2 days before meeting
B	21 days	60 days	30 days before meeting/WRO	2 days before meeting
B(EOP)	14 days	70 days	50 days before meeting/WRO	5 days before meeting
C	21 days	75 days	47 days before meeting/WRO	5 days before meeting
C (new surrogate endpoints)	21 days	75 days	At time of request	5 days before meeting
D	**14 days**	**50 days**	**At time of request**	**5 days before meeting**
INTERACT	**21 days**	**75 days**	**At time of request**	**5 days before meeting**
Follow-Up Opportunity	• **Request must be received within 20 days after FDA issues minutes/written responses** • **FDA responds within 20 days of receipt**		**N/A**	**N/A**

BsUFA MEETINGS:
What's New under BsUFA III?

BsUFA III Meeting Changes

- **New Meeting Types or Meeting Changes:**
  - Biological Product Development (BPD) Type 2 mtgs: now Type 2b
  - BPD Type 2a: narrow set of issues
  - Follow-up Opportunity
  - Biosimilar Initial Advisory (BIA): analytical data comparing proposed biosimilar to US reference product no longer required
  - BPD Type 4 meeting package timeline: submit 14 days after mtg request; previously submitted with mtg request
  - Initial BPD fee (after FDA grants the first BPD meeting or upon submission of an IND): timeline to pay was increased from 5 to 7 days

BsUFA Meeting Types and Goal Dates

Meeting Type	Respond Within:	Meeting Scheduled/ WRO Due Within:	Background Package Due:	Preliminary Comments Due:
Biosimilar Initial Advisory	21 days	75 days	With submission	2 days before meeting
BPD Type 1	14 days	30 days	With submission	2 days before meeting
BPD Type 2a	**21 days**	**60 days**	**With submission**	**2 days before meeting**
BPD Type 2b	21 days	90 days	With submission	5 days before meeting
BPD Type 3	21 days	120 days	With submission	5 days before meeting
BPD Type 4	21 days	60 days	**Within 14 days from receipt**	2 days before meeting
Follow-Up Opportunity	• **Request must be received within 20 days after FDA issues minutes/written responses** • **FDA responds within 20 days of receipt**		N/A	N/A

OTC MONOGRAPH MEETINGS

What Types of Monograph Meetings are Available?

- Meeting Types:
  - Type X
  - Type Y
  - Type Z

An Overview of Monograph Meeting Types

Type X:

- Necessary for an otherwise stalled OTC monograph order development program to proceed
- Important safety issue that needs immediate action

Type Y:

- Overall data recommendations
- Pre-OTC monograph Order Request (OMOR) submission

Type Z:

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

Monograph Meeting Types and Goal Dates

Meeting Type	Respond Within:	Meeting Scheduled/ WRO Due Within:	Meeting Package Due:	Preliminary Responses Due:
X	14 days	30 days	At time of request	N/A
Y	14 days	70 days	50 days before meeting/WRO	Internal goal: 5 days before meeting
Z	21 days	75 days	47 days before meeting/WRO	Internal goal: 5 days before meeting

MEETING FORMATS AND UPDATES

What Meeting Formats are Available?

- Meeting Formats:
  - Face-to-Face
    - In-Person (will include a hybrid component)
    - Virtual* (videoconference)
  - Teleconference (no video)
  - Written Responses Only (WRO)

***New**

In-Person/Hybrid Formal Meetings

- In early 2023, CDER began transitioning to a hybrid workplace enabling face-to-face formal meetings between FDA and Industry

- Phase 1 February 13, 2023: Type A, BPD 1, and Type X meeting requests. Face-to-face meeting requests for other meeting types, if granted, will be held as virtual (videoconference) meetings (i.e., the in-person format will not be considered).

- Phased approach requiring conference room upgrades

- Phase 2 of this transition would permit additional face-to-face formal meeting types to be considered for in-person scheduling.

- The final phase of this transition will enable any face-to-face formal meeting to be considered for in-person format.

MEETING TIPS and BEST PRACTICES for INDUSTRY

Tips and Best Practices: Before the Meeting

- Utilize guidance documents to the fullest
- Communicate with RPM; ask questions before submitting
- Notify RPM of any changes to meeting attendees
- Meeting package should be clear, concise and focused
- Alert RPM of revised agenda after receipt of FDA's preliminary comments; do not add new topics or issues to the original agenda
- Provide any meeting slides/handouts, if possible before the meeting

Tips and Best Practices: During the Meeting

- Take the lead
  - Be cognizant of the time for any presentations
  - Make sure that your questions have been addressed
  - Summarize key discussion points, agreements, action items

RESOURCES

Resources

- Draft Guidance for Industry: Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products
- Draft Guidance for Industry: Formal Meetings Between the FDA and Sponsors or Applicants of BsUFA Products
- Draft Guidance for Industry: Formal Meetings Between the FDA and Sponsors or Requestors of Over-the-Counter Monograph Drugs
- OTC Monograph Reform: Overview of Draft Guidance for Formal Meetings - 03/29/2022 | FDA

Resources con't

- PDUFA Drug User Fee Amendments website
- Biosimilar User Fee Amendments website
- Over-The-Counter Monograph Drug User Fee Program (OMUFA) website
- Update on In-Person Face-to-Face Formal Meetings with FDA

Questions?

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Backup slides

- **Type A**: Stalled development programs or safety issue: dispute resolution, clinical hold, nonagreement to SPA, post-action for complete response or RTF
- **Type B**: Pre-IND/NDA/BLA/EUA (End of Phase meetings)
- **Type C**: Generally everything else; guidance or advice
- **Type C Surrogate** meetings were negotiated under PDUFA VI. These early consultation meetings are for development programs where the sponsor intends to use a biomarker as a new surrogate endpoint that has never been previously used as the primary basis for product approval in the proposed context of use.
- For PIND, Type C, D, and Interact: may request F2F but FDA may handle as WRO

Backup slides

- **Biosimilar Initial Advisory** Meeting is an initial assessment limited to a general discussion regarding whether licensure under section 351(k) of the Public Health Service Act may be feasible for a particular product. Only 1 BIA meeting may be granted per program. Can be done as WRO, F2F or tcon
- **BPD Type 1** Meeting is a meeting which is necessary for an otherwise stalled drug development program to proceed (e.g. meeting to discuss clinical holds, dispute resolution meeting), a special protocol assessment meeting, or a meeting to address an important safety issue.
- **BPD Type 2a** Meeting is a meeting focused on a narrow set of issues (e.g., often one, but not more than two issues and associated questions), requiring input from no more than 3 disciplines or review divisions. Must have had BIA or other BPD meeting first. **FDA has the option with these meetings to convert F2F requests to WRO.**
- **BPD Type 2b** Meeting is a meeting to discuss a specific issue (e.g., proposed study design or endpoints) or questions where FDA will provide advice regarding an ongoing biosimilar biological product development program. This meeting may include substantive review of summary data, but does not include review of full study reports.
- **BPD Type 3** Meeting is an in depth data review and advice meeting regarding an ongoing biosimilar biological product development program. This meeting includes substantive review of full study reports, FDA advice regarding the similarity between the proposed biosimilar biological product and the reference product, and FDA advice regarding additional studies, including design and analysis.
- **BPD Type 4** Meeting is a pre-submission meeting to discuss the format and content of a complete application for an original biosimilar biological product application under the Program or supplement submitted under 351(k) of the PHS Act.