Meetings with CDER

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Guidance for Industry: "Formal Meetings with Sponsors and Applicants for PDUFA Products"

- Product name and application number (if applicable)
- Chemical name and structure
- Proposed indication (s)
- The type of meeting being requested (e.g., Type A, Type B, or Type C)

Guidance for Industry (cont)

- A brief statement of the purpose of the meeting
- A list of specific objectives/outcomes expected from the meeting
- A preliminary proposed agenda
- A draft list of questions, grouped by discipline
- A list of all individuals (including titles) who will attend the meeting

Guidance for Industry (cont)

- A list of Agency staff requested by the sponsor or applicant to participate in the proposed meeting
- The approximate date on which supporting documentation will be sent to the Division
- Suggested dates and times (e.g., morning or afternoon) for the meeting
  - http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm093430.htm

Types of Meetings

Type	A	B	C
Confirmation of scheduling	14 days	21 days	21 days
Held no later than	30 days	60 days	75 days
Briefing package	With meeting request	1 month	1 month
Description, Comments	Dispute resolution, Clinical holds, Special Protocol Assessment (SPA), Post action meeting (3 months of the action)	preIND^, EOP1, EOP2, Pre NDA/BLA, REMS* or PMRs**	Any other than type A or B Can be granted as written response only (WRO)

*Risk Evaluation and Mitigation Strategy ** Post Marketing Requirements ^ can be granted as WRO

How do I request a meeting?

- All pre-IND submissions addressed directly to the Chief Project Management Staff (CPMS) or other designated personnel until a PIND file is opened
  - http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/InvestigationalNewDrugINDApplication/Overview/UCM166356.pdf
- Once the file is opened, send the Meeting Request to the file (Central Document Room)

Establishing the meeting

- The assigned Regulatory Project Manager (RPM) will contact sponsor to reach agreement on date/time of the meeting
- Correspondence is issued with information on date/time/location/attendees
- Foreign visitor form
- Briefing document
  - Type A meeting with meeting request
  - Type B or C meeting-a month before the meeting or goal date for Written Responses Only (WRO)

BRIEFING DOCUMENTS (briefing package)

- Not too big, not too small”
- Table of contents
- **List of questions**
- Organized with tabs
- Submitted on time
- Adequate number of copies
- Electronic vs. paper

Pre-IND Meeting

Briefing document

- More detailed than the meeting request
- Provide summary information related to the product
- Organized according to the agenda/questions

EOP2 Meeting

Briefing document

- Summaries of Phase 1 and Phase 2 investigations
- Summary information on plans for Phase 3 trials
- Specific Protocols for Phase 3 trials
  - Choice of comparator
  - Definition and time point for assessment of primary endpoint
  - Statistical analysis approach and criterion for success and failures of the primary efficacy and secondary endpoints
  - Discussion of Pediatric Study (ies)
  - Size of the safety database

EOP2 Meeting
Briefing document

- Plans for Pediatric Studies to address PREA
- Plans for the REMS
- Plans for additional non-clinical studies (if required)

Pre NDA/BLA Meeting

Briefing Document

- Summary of the data from completed pivotal trials
- Proposed Indication
- Manufacturing information on the products used in the studies and product intended form distribution, if different
- Discussion on Request Priority Review, Information on Fast Track and Orphan designation, if applicable
- Development plan for complying with PREA
- Proposed format of the submission
- Timeline for submission

Pre NDA/BLA Meeting-

Briefing Document

- PDUFA V Product (NME and BLA)
  - Pre-submission meeting
  - Include a proposal for the content of a complete application
  - Any minor components to be submitted within 30 days

Meetings

- For every external meeting there is at least one internal team meeting
  - Pre-meeting/internal meeting
  - Usually, preliminary answers to questions are sent to the sponsor 24-48 hours before the meeting
- Industry/Sponsor external meeting

Before the meeting

- Work with RPM to establish agreeable agenda and acceptable list of questions
- Notify RPM of any last minute changes (list of attendees, audio/visual equipment)
  - Foreign visitors
  - Lobby Guard
- Provide the Division with any meeting hand-outs and/or slides, if possible before the meeting

During the meeting

- THIS IS YOUR MEETING
- Take the lead
  - Make sure that your questions have been addressed
  - Summarize key discussion points, agreements, and action items

Post meeting

- Official minutes of the meeting will be issued by FDA within 30 days of the meeting
  - Written Responses Only (WRO) issued no later than 60 days of receipt of the meeting request
- Review minutes and notify Division of any discrepancies/clarifications
- Follow-up on any requests

Meetings are not appropriate when

- Information can be condensed in a summary
- Timing is premature
- Right people are not present
- There is missing information

General comments

- Face to face meetings are not the only way to obtain feedback and advice
- Schedule meetings to discuss specific issues
- Do not schedule meeting to obtain pre-review of data
- “What ifs” or hypothetical situations are difficult to address
- The Agency will provide guidance/comments on your proposals
- Utilize guidance documents to the fullest

Tips

- Communicate clearly with the FDA RPM
- Work with RPM to determine mutually agreed upon time/day for the meeting
- Discuss with RPM how many copies of the briefing package are needed
- Organize the briefing package with tabs
- Submit focused questions
- Electronic submission vs. paper

More tips

- Update changes in attendees
- Presentations?
- Do not add new topics or issues to the original agenda
- Do not ask open ended questions
- **Make sure all your concerns/questions have been addressed (or acknowledged) before you leave the meeting**

PDUFA V- "The Program"

- Applies to NMEs (new molecular entities) and BLAs (Biologic License Applications) received 10/1/12 to 9/30/17
  - http://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM304793.pdf

PDUFA V- “The Program”

- Pre-submission meeting (pre-NDA, pre-BLA)
  - Agreement on content of a complete application
  - Submission of limited number of application components no later than 30 calendar days after submission of the NDA/BLA

PDUFA V- “The Program”

- Mid cycle communication (MCC)
  - Scheduled by FDA
  - FDA will call applicant within 2 weeks of the mid cycle meeting
  - Non PDUFA Meeting

PDUFA V- "The Program"

- Late cycle meeting (LCM)
  - Scheduled by FDA
    - No later than 3 months (standard review) or 2 months (priority review) before PDUFA goal date
    - If Advisory Committee, no later than12 days before such meeting
  - FDA provides the briefing document

BsUFA (Biosimilar User Fee Act) Meetings

- Biosimilar Initial Advisory Meeting
- Biosimilar Product Development Type 1
- Biosimilar Product Development Type 2
- Biosimilar Product Development Type 3
- Biosimilar Product Development Type 4
- Non PDUFA Meeting

www.fda.gov/bsufa

Biosimilar Initial Advisory Meeting

- No fee
- Response goal date within 21 days of FDA receipt of a meeting request with briefing document
- Held with 90 calendar days of FDA receipt of meeting request
- Minutes issued within 30 days of the meeting

Biosimilar Product Development Type 1

- Necessary for an otherwise stalled biosimilar development program
- FDA will not hold the meeting unless the yearly fee has been paid
- Meeting response within 14 days of FDA receipt of a written meeting request and meeting package
- Held within 30 days of the meeting request
- Minutes issued within 30 days of the meeting

Biosimilar Product Development Type 2

- Targeted advice regarding a discrete issue
- May include review of data but not review of full study reports
- FDA will not hold the meeting unless the yearly fee has been paid
- Meeting response within 21 days of FDA receipt of a written meeting request and meeting package
- Held within 75 days of the meeting request
- Minutes issued within 30 days of the meeting

Biosimilar Product Development Type 3

- In depth review of study reports
- FDA will not hold the meeting unless the yearly fee has been paid
- Meeting response within 21 days of FDA receipt of a written meeting request and meeting package
- Held within 120 days of the meeting request
- Minutes issued within 30 days of the meeting

Biosimilar Product Development Type 4

- Discussion of format and content of a biosimilar product application
- FDA will not hold the meeting unless the yearly fee has been paid
- Meeting response within 21 days of FDA receipt of a written meeting request and meeting package
- Held within 60 days of the meeting request
- Minutes issued within 30 days of the meeting

Location

Food and Drug Administration

Center for Drug Evaluation and Research

10903 New Hampshire Avenue

Silver Spring, MD 20993

Regulatory submissions

Food and Drug Administration

Center for Drug Evaluation and Research

Central Document Room

(Therapeutic Biologics Document Room)

5901-B Ammendale Road

Beltsville, MD 20705-1266

Resources

- www.fda.gov
- www.fda.gov/drugs
- www.fda.gov/BiologicsBloodVaccines
- www.fda.gov/bsufa
- www.fda.gov/cder/guidance
- http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved
- http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm272170.htm