

Regulatory Education
for Industry (REdI)
Fall 2015

**FDA SMALL
BUSINESS** AND
INDUSTRY ASSISTANCE
REdI Conference

Meetings with CDER

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(DTOP)

Office of Antimicrobial Products (OAP),
Office of New Drugs (OND)

Center for Drug Evaluation and Research (CDER)



Meetings with CDER

- Formal Meetings
 - Primer
 - Best Practices
- Enhanced Communication-PDUFA V “The Program”
- Biosimilar Products
- Critical Path Innovation



Formal Meetings with CDER

- What are *formal* meetings with the FDA?
- Types of formal meetings
- Requesting and establishing a formal meeting
- Pre-Meetings- what do I need to know about them
- Conduct of the formal meeting



What are Formal Meetings?

Any meeting requested by a sponsor or applicant following the [Guidance for Industry – Formal Meetings Between the FDA and Sponsor or Applicants of PDUFA Products.](#)

Relate to the development and review of drug or biological products regulated by the CDER or CBER



Types of Meetings

Type	A	B	C
Decision to Grant/Deny	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 post-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?

- Written correspondence
 - To the file (IND, NDA, BLA)
 - No file
 - Central Document Room
 - E-mail or fax to the Division

IND - Investigational New Drug

NDA - New Drug Application

BLA - Biologic License Application



Tips & Best Practices

- Check CDER Organizational Chart
 - Therapeutic areas
 - <http://www.fda.gov/downloads/AboutFDA/CentersOffices/OrganizationCharts/UCM439876.pdf>
- Contact the Chief Project Manager (CPMS) informally before submitting a request
- Request addressed to the Division Director
- Refer to the Guidance for content and organization
 - <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM153222.pdf>



Content of a Meeting Request

- Product name
- Application number (if applicable)
- Chemical name and structure
- Proposed indication(s) or context of product development
- Type of meeting being requested
- Brief statement of purpose and objectives



Content of a Meeting Request

- Proposed agenda
- Proposed questions, grouped by discipline
- List of attendees, with titles and affiliation
- List of FDA staff asked to participate
- Suggested dates and times
- Format of the meeting (Face to face, teleconference, video conference)



Scheduling the Meeting

- Regulatory Project Manager (RPM), will contact the sponsor to reach agreement on date/time of the meeting
- Communication (letter, fax, e-mail, phone call) acknowledging date/time, location, attendees



Scheduling the Meeting

- Arrival and meeting protocols
 - Foreign Visitors
 - IT equipment
 - Lobby Guard



Scheduling the Meeting

- Briefing package
 - Number of copies
 - “Not too big, not too small”
 - Table of contents
 - List of questions
 - Organized with tabs
 - Submitted on time
 - Paper vs. electronic



Briefing Package Content

- Summary (ies) of available information
- Additional information needed to develop responses to the requested question
- Submission timeline
 - Type A Meeting- At the time of the Meeting request
 - Type B or C Meetings- 1 month before the meeting or due date for WRO



Briefing Package Content

- Product name and application number
- Chemical name and structure
- Proposed indication
- Dosage form, route of administration, and dosing regiment
- Purpose of the meeting
- Updated list of attendees, affiliation and titles



Briefing Package Content

- Background section
 - Brief history of the development program
 - Status of product development
- Proposed Agenda
- Final list of questions, organized by discipline, with a brief summary to provide context
- Data to support discussion



FDA Internal Pre-Meetings

- For every external meeting there is at least one internal meeting
 - Team discusses and reaches agreement on responses
 - Usually, preliminary responses sent no later than 48 hours before the meeting with sponsors



Meeting Best Practices

- Work with RPM to establish an agreeable agenda and list of questions
- Notify the RPM of any last minutes changes
 - List of attendees (Lobby Guard)
 - Need for audio/visual equipment
 - Meeting format
- Provide any meeting hand-outs and/or slides, if possible before the meeting



Meeting Best Practices

- Schedule Meetings to discuss specific issues
 - Submit focused questions
 - Avoid open ended questions
 - “What ifs” or hypothetical situations are difficult to address
- Do not schedule Meetings to pre-review data
- Utilize Guidance documents to the fullest



Conduct of the Formal Meeting

- Face to Face
- Teleconference or Videoconference
- Written Responses Only (WRO)





Conduct of the Meeting

- Chaired by FDA-Introductions
- Presentations are generally not expected or required
- New data or information may not be commented or agreed upon during the meeting



Conduct of the Meeting

Key “Take-Away” Message

THIS IS YOUR MEETING

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



After the Meeting

- Official Minutes are issued within 30-days
- Review Minutes and notify the Division of any discrepancies
- Follow up on any requests or action items



CDER Meetings Poll

DRG-D2S8 Poll #1 ☰

How many PDUFA meetings do you think CDER had in 2014?

<input type="radio"/> 100 - 250	<div style="width: 100%; height: 15px; background-color: #ccc;"></div>	0%	(0)
<input type="radio"/> 250 - 500	<div style="width: 100%; height: 15px; background-color: #ccc;"></div>	0%	(0)
<input type="radio"/> 500 - 1,000	<div style="width: 100%; height: 15px; background-color: #ccc;"></div>	0%	(0)
<input type="radio"/> 1,000 - 2,000	<div style="width: 100%; height: 15px; background-color: #ccc;"></div>	0%	(0)
<input type="radio"/> More than 2,000	<div style="width: 100%; height: 15px; background-color: #ccc;"></div>	0%	(0)
<input checked="" type="radio"/> No Vote			

Broadcast Results



PDUFA Meetings in CDER

In the 2014 fiscal year

RECEIVED 2608 meeting requests

GRANTED 2493 meetings

<http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/UserFeeReports/PerformanceReports/ucm2007449.htm>



PDUFA V-“The Program”

- Applies to NMEs (new molecular entities) and Original BLAs (Biologic License Applications) received 10/1/12 to 9/30/17
 - <http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm327030.htm>



PDUFA V-“The Program”

- Pre-submission meeting (pre-NDA, pre-BLA)
 - Agreement on content of a complete application
 - Agreement on the submission of a 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



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 than 12 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

- An initial assessment limited to a general discussion regarding whether the biosimilar licensure pathway may be feasible for a particular product, and, if so, general advice on the expected content of the development program.
- No fee
- Response goal date within 21 days of FDA receipt of a meeting request with briefing document
- Held within 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 BPD 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 product development
- May include review of summary data but not review of full study reports
- FDA will not hold the meeting unless the BPD 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 data including full study reports
- FDA will not hold the meeting unless the BPD 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 BPD 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



Critical Path Innovation Meeting

- New CDER program
- Nonbinding scientific discussions
 - potential biomarkers and clinical outcome assessments
 - natural history studies
 - emerging technologies (not manufacturing technology)
 - novel clinical trial designs and methods
- Not about specific approval pathways

<http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DrugInnovation/ucm395888.htm>



Division Contacts

Office of Drug Evaluation I (ODE I)

Division of Neurology Products (DNP)	301-796-2250
Division of Psychiatry Products (DPP)	301-796-2260
Division of Cardiovascular and Renal Products (DCRP)	301-796-2240

Office of Drug Evaluation II (ODE II)

Division of Metabolic and Endocrine Products (DMEP)	301-796-2290
Division of Pulmonary, Allergy and Rheumatology Products (DPARP)	301-796-2300
Division of Anesthesia, Analgesia, and Addiction Products (DAAAP)	301-796-2280

Office of Drug Evaluation III (ODE III)

Division of Gastroenterology and Inborn Errors Products (DGIEP)	301-796-2120
Division of Bone, Urologic, and Reproductive Products (DBRUP)	301-796-2130
Division of Dermatology and Dental Products (DDDP)	301-796-2110



Division Contacts

Office of Drug Evaluation IV (ODE IV)

Division of Non Prescription Drug Products (DNBP)	301-796-2080
Division of Medical Imaging Products (DMIP)	301-796-2050
Division of Pediatric And Maternal Health (DPMH)	301-796-2200

Office of Antimicrobial Products (OAP)

Division of Anti-Infective Products (DAIP)	301-796-1400
Division of Antiviral Products (DAVP)	301-796-1500
Division of Transplant and Ophthalmology Products (DTOP)	301-796-1600



Division Contacts

Office of Hematology Oncology Products (OHOP)

Division of Oncology Products I (DOP1) 301-796-2330

Breast, Gynecologic, Genitourinary, Supportive care (non-hematologic)

Division of Oncology Products II (DOP2) 301-796-2320

*Gastrointestinal, Lung/Head & Neck, Neuro-oncology/Rare cancers/
Pediatric Solid Tumor, Melanoma/Sarcoma*

Division of Hematology Products (DHP) 301-796-7550

*Benign hematology, Hematologic malignancies, Hematology support,
Pediatric Hematology*

Division of Hematology Oncology Toxicology (DHOT) 301-796-2340

Nonclinical Review Division for Hematology/Oncology Products



Meeting Location

Food and Drug Administration

Center for Drug Evaluation and Research

10903 New Hampshire Ave.

Silver Spring, MD 20993

<http://www.fda.gov/aboutfda/workingatfda/buildingsandfacilities/whiteoakcampusinformation/ucm241748.htm>



Central Document Room

Food and Drug Administration

Center for Drug Evaluation and Research

Central 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/DevelopmentApprovalProcesses/HowDrugsareDevelopedandApproved>
- <http://www.fda.gov/Drugs/NewsEvents/ucm132703.htm>



QUESTIONS ?

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Please complete the session survey:

surveymonkey.com/r/DRG-D2S8