Formal Meetings for PDUFA Products and Best Practices for Communication During Drug Development

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May 15, 2017

Guidance Background

Drafts Published in 2015:

- *Best Practices for Communication Between IND Sponsors and FDA During Drug Development Guidance for Industry and Review Staff* - December
- *Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products* - March

Guidance Background Cont'd

Published in December 2017:

- *Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products* – Draft
- *Best Practices for Communication Between IND Sponsors and FDA During Drug Development Guidance for Industry and Review Staff* – Final

Type A Meeting

Are necessary for an otherwise stalled product development program to proceed or to address an important safety issue.

Examples:

- Dispute Resolution
- Clinical Holds
- Post action meetings (requested within 3 months of issuance of a complete response letter)

Type B Meeting

Examples:

- Pre-IND
- Pre-emergency use authorization meetings
- Pre-NDA/BLA
- Post action meetings (requested 3 or more months after the of issuance of a complete response letter)

Type B (EOP) Meeting

- Certain end-of-phase 1 meetings
- End-of-phase 2 or pre-phase 3 meetings

Type C Meeting

A Type C meeting is any meeting other than Type A, Type B, or Type B (EOP) meeting regarding the development and review of a product.

Including meetings to facilitate early consultations on the use of a biomarker as a new surrogate endpoint that has never been previously used at the primary basis for product approval in the proposed context of use.

Meeting Request Content

A written request must include:

- Brief statement of purpose
- Proposed meeting format
- List of specific objectives/outcomes
- Proposed agenda, with timeframes for each item
- List of sponsor related attendees
- List of requested FDA participants/disciplines
- Date meeting package will be sent

Meeting Request Response Time

Meeting Type	Response Time (calendar days)
A	14
B	21
B (EOP)	14 NEW
C	21

Scheduling Meetings

Meeting Type	Scheduling or Written Response Time (calendar days from receipt of request)
A	30 days
B	60 days
B(EOP)	70 days 
C	75 days

Meeting Packages

Meeting Type	Receipt of Meeting Package (calendar days before the meeting date or expected written response)
A	At the time of the request
B	30 NEW
B (EOP)	50* NEW
C	47* NEW

*If the scheduled date is earlier than the specified timelines, the meeting package will be no earlier than 6 days for Type B(EOP) and 7 days for Type C.

Preliminary Responses

Meeting Type	Preliminary Responses (no later than before meeting)
A	2 days
B	2 days
B (EOP)	5 days NEW
C	5 days NEW

Note: Not applicable to written responses only

Response to Preliminary Responses

Meeting Type	Response to Preliminary Responses (no later than after receipt of preliminary responses)
A	—
B	—
B(EOP)	3 days NEW
C	3 days NEW

Note: Not applicable to written responses only

FDA's Communication Philosophy

- FDA and IND sponsors have a shared goal of early availability of safe, effective, and high-quality drugs

- different primary responsibilities

FDA's Communication Philosophy

Sponsors' Primary IND Responsibilities

- Managing the overall drug development
- Soliciting input and guidance from FDA
- Determining the nature and timing of regulatory submissions
- Providing well-organized and complete submissions for review

FDA's Communication Philosophy

FDA's Primary IND Responsibilities

- Ensuring
  - safety and rights of subjects
  - quality of the scientific evaluation of drugs
- Enforcing
  - good clinical practice
  - enforcing human subject protection requirements

FDA's Communication Philosophy

FDA's Primary IND Responsibilities Cont'd

- Reviewing IND submissions
- Providing feedback on trials and development programs
- Taking regulatory actions

FDA's Communication Philosophy

FDA's Primary IND Responsibilities Cont'd

- Promoting the advancement of regulatory science by:
  - authoring FDA and international guidances
  - conducting and participating in public workshops
  - collaborating with academia
  - publishing in medical and trade journals
  - presenting at professional conferences

Biosimilars

BsUFA II commitment to explicitly state the guidance parameters apply communications during biosimilar biological product development (BPD).

Biosimilars Meetings

BsUFA critical juncture meetings include Biosimilar Initial Advisory (BIA) and BPD Type 1 through Type 4 meetings.

- Are intended to support an iterative process of interactions during the development phase.
- Are based on the stage of development and amount and type of data and information provided.

BIA Meeting

An initial assessment limited to general discussion; does not include any meeting that involves substantive review of summary data or full study reports.

BPD Type 1 Meeting

A meeting that is necessary for an otherwise stalled drug development program to proceed (e.g., clinical hold discussion, dispute resolution, special protocol assessment, or addresses an important safety issue.)

BPD Type 2 Meeting

A meeting to discuss a specific issue or questions where targeted advice will be provided. Can include substantive review of summary data, but does not include review of full study reports.

BPD Type 3 Meeting

An in-depth data review and advice meeting for an ongoing BPD program; includes:

- substantive review of full study reports
- advice regarding the similarity between the proposed product and reference product
- advice regarding additional studies, including design and analysis.

BPD Type 4 Meeting

A presubmission 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.

Resources for Sponsors

FDA develops and maintains Web pages, portals, and databases, and participates in interactive media as a means of providing self-service tools for its stakeholders.

Sponsor use of these tools allows for more effective utilization of limited FDA resources in providing advice on scientific and regulatory issues that fall outside of established guidance, policy, and procedures.

Resources for Sponsors

- FDA Guidances
- FDA Policy and Procedures
- FDA Basics for Industry
- FDA Interactive Media
- FDA Presentations
- FDA Labeling and Approvals
- FDA Rules and Regulations
- FDA-Funded Scientific Research Results NEW
- Code of Federal Regulations

FDA Guidances

Guidance documents explain our current thinking on policy, scientific, and/or regulatory issues.

FDA Guidance web page

https://www.fda.gov/Drugs/GuidancecomplianceRegulatoryInformation/Guidances/default.htm

FDA Policy and Procedures

CDER MAPPs describe internal policies and procedures.

CDER MAPPs web page

https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ManualofPoliciesProcedures/default.htm

FDA Basics for Industry

Provides basic information about FDA regulatory processes and resources to better understand how to work with FDA.

Subject Areas:

- Topics A-Z Index
- Popular Content
- Submit Questions and Comments
- Industry Frequently Asked Questions

FDA Basics for Industry web page

https://www.fda.gov/ForIndustry/FDABasicsforIndustry/default.htm

FDA Interactive Media

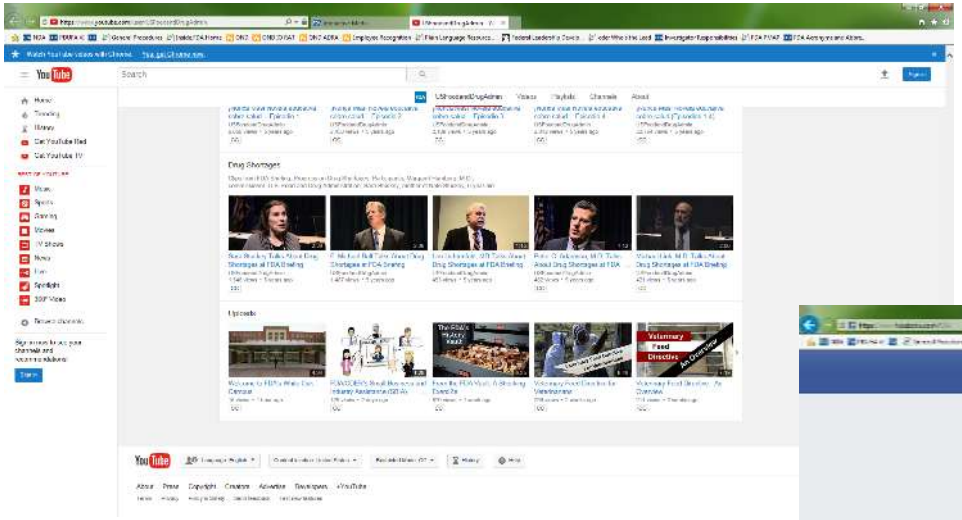
FDA uses interactive media to communicate information about:

- emerging science
- new policies and procedures
- public advisory committee meetings
- workshops

Interactive Media web page

https://www.fda.gov/NewsEvents/InteractiveMedia/default.htm

FDA on YouTube, Facebook, and Twitter



FDA Presentations - CDER

Topics can range from:

- users fees
- to drug advertising and marketing
- to genomics
- to over-the-counter products

Meeting Presentations (Drugs) web page
https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm074833.htm

FDA Labeling and Approvals - CDER

CDER's Drugs@FDA database contains information about CDER regulated FDA-approved products.

- search by drug, active ingredient, or application
- browse by drug
- drug approval reports by month
  - ✓ original NDAs and BLAs
  - ✓ supplements to NDAs and BLAs
  - ✓ original ANDAs
  - ✓ tentative approvals

Drugs@FDA database web page
https://www.accessdata.fda.gov/scripts/cder/daf/

FDA Rules and Regulations

Web page contains information about:

- notice and comment on rulemaking
- review of proposed and final rules
- related resources (e.g. what FDA regulates)

FDA Rules and Regulations web page

https://www.fda.gov/regulatoryinformation/rulesregulations/default.htm

FDA-Funded Scientific Research Results

Philosophy:

- broad availability of scientific information and underlying data allow for the critical review, replication, and verification of findings
- accessible and analyzable findings and supporting digital data promote robust and open communication
- bolsters scientific credibility and regulatory decision making based on those findings

FDA-Funded Scientific Research Results Cont'd

In the future the web page will provide educational resources about public access policies and the tools for complying.

Public Access to Results of FDA-Funded Scientific Research web page

https://www.fda.gov/ScienceResearch/AboutScienceResearchatFDA/ucm433459.htm

Code of Federal Regulations

The Code of Federal Regulations (CFR) codifies the Federal Government rules published in the Federal Register.

The e-CFR is an unofficial compilation of CFR material and Federal Register amendments.

e-CFR web page

https://www.ecfr.gov/cgi-bin/ECFR?page=browse

FDA - Additional Contacts

Use for basic or procedural drug development questions ***not*** directly linked to an existing or planned development program.

CDER - Additional Contacts

- Biomarker Qualification Program 

- Controlled Substance Staff
- Division of Drug Information
- Division of Pediatric and Maternal Health
- Emerging Technology Team 

- Enhanced Communication Team
- Import/Export
- Office of Pharmaceutical Quality 

- Ombudsman
- Rare Diseases Program
- Small Business & Industry Assistance
- Therapeutic Biologics and Biosimilars Staff 

Biomarker Qualification Program

Encourages biomarker development by providing a framework for development and regulatory acceptance.

Biomarker Qualification Program web page

https://www.fda.gov/Drugs/DevelopmentApprovalProcess/DrugDevelopmentToolsQualificationProgram/BiomarkerQualificationProgram/ucm20086360.htm

Controlled Substance Staff

Responds to inquiries about the drug scheduling process and the study of abuse potential in animal and human studies.

Controlled Substance Staff web page

https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm180753.htm

Division of Drug Information

Provides expert advice and guidance regarding all aspects of CDER activities to consumers, health care professionals, insurance companies, regulated industry, academia, law enforcement, FDA, and other government agencies.

Division of Drug Information web page

https://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cder/ucm082585.htm

Division of Pediatric and Maternal Health

Collaborates with internal and external stakeholders to develop clinically relevant, evidence-based labeling and other communications that facilitate informed use of medicines in children and women of childbearing potential.

- Pediatric email: pedsdrugs@fda.hhs.gov
- Maternal health email: cder.pmhs@fda.hhs.gov

Emerging Technology Team

Responds to external inquiries on novel technologies.

Emerging Technology Team web page

https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm523228.htm

Enhanced Communication Team

- Responds to general questions about the drug review process
- Clarifies which OND review division to contact
- Provides assistance resolving communication challenges with the review team

Enhanced Communication Team web page
https://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm327281.htm

Import/Export

Responds to questions related to:

- general import compliance
- export certificate
- compliance

Import Export Compliance Branch web page
https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/ImportsandExportsCompliance/default.htm

Office Of Pharmaceutical Quality

Responds to product quality related inquiries.

Office of Pharmaceutical Quality web page
https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm418347.htm

Ombudsman

Provides:

- informal advice
- assistance with issues that arise in the context of the regulatory process
- feedback about CDER's programs and overall performance

Note: Upon request, communication with the Ombudsman will be kept confidential.

CDER Ombudsman web page
https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ContactCDER/CDEROmbudsman/default.htm

Rare Diseases Program

- Exchanges scientific and regulatory information with international regulatory agencies
- Promotes the development of treatments by collaborating with internal and external rare disease stakeholders

Rare Diseases Program web page
https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm221248.htm

Small Business and Industry Assistance

Provides human drug product development and regulation information.

Small Business and Industry Assistance web page
https://www.fda.gov/Drugs/DevelopmentApprovalProcess/SmallBusinessAssistance/default.htm

Therapeutic Biologics and Biosimilars Staff

Ensures consistency in the scientific and regulatory approach and advice regarding development programs for therapeutic biologics and for proposed biosimilar products.

Therapeutic Biologics and Biosimilars web page

https://www.fda.gov/biosimilars

email:

ONDTherapeuticBiologicsandBiosimilarsPMStaff@fda.hhs.gov

Office of Special Medical Programs – Additional Contacts

Office of Special Medical Programs

- Advisory Committee Oversight and Management Staff
- Office of Combination Products
- Office of Good Clinical Practice
- Office of Orphan Products Development
- Office of Pediatric Therapeutics

Advisory Committee Oversight and Management Staff

Provides guidance and assistance on the establishment, staffing, and management of public advisory committees.

- calendars
- meeting materials

Advisory Committees web page
https://www.fda.gov/AdvisoryCommittees/default.htm

Office of Combination Products

- Addresses premarketing review and postmarketing regulation questions
- Provides combination product training to FDA staff and industry
- Classifies products

Office of Combination Products web page

https://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsandtobacco/officeofscienceandhealthcoordination/ucm2018184.htm

Office of Good Clinical Practice

- Plans and conducts training and outreach programs
- Responds to good clinical practice and human safety protection questions

Office of Good Clinical Practice web page

https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/OfficeofScienceandHealthCoordination/ucm2018191.htm

Office of Orphan Products Development

Programs:

- Orphan Drug Designation
- Humanitarian Use Device
- Rare Pediatric Disease Priority Review Voucher
- Orphan Products Grants
- Pediatric Device Consortium Grants
- Orphan Products Natural History Grants

Office of Orphan Products Development web page

https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/OfficeofScienceandHealthCoordination/ucm2018190.htm

Office of Pediatric Therapeutics

Programs:

- Scientific Activities
- Ethics
- Safety
- International
- Neonatology

Office of Pediatric Therapeutics web page

https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/OfficeofScienceandHealthCoordination/ucm2018186.htm

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THank
YOU!