

US

Formal Meetings with FDA



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FDA encourages sponsors to consult the agency during their products' development program through one of the formal meetings described in the chart below. The main goal of these meetings is to improve the quality of products' development and increase the likelihood of getting the products approved by FDA quickly.

What is a formal meeting with FDA?

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*. Meetings that are related to the development and review of drug or biological products regulated by the CDER or CBER.

What are the types of meetings with FDA?

There are three different types of formal meetings that can occur between the FDA and sponsors. Each type of meeting is subject to different procedures and processes described below.

MEETING TYPE	PURPOSE	APPLICATIONS
Type A Meetings	Type A meetings are meetings that are “necessary for an otherwise stalled product development program to proceed (a critical path meeting) or to address an important safety issue	<ul style="list-style-type: none"> Dispute resolution Discuss clinical holds Discuss special protocol assessment after receiving FDA's response to protocols submitted under the special protocol assessment procedures. Discuss post-action when requested within three months after receiving an FDA regulatory action other than approval.
Type B Meetings	Type B meetings are milestone meetings.	<p>Pre-IND Meetings</p> <ul style="list-style-type: none"> Pre-emergency use authorization End-of-phase 1 <p>End-of-phase 2/pre-phase 3 meetings</p> <p>Pre-NDA/pre-BLA meetings</p> <ul style="list-style-type: none"> Post-action meetings when requested within three months after receiving an FDA regulatory action other than approval. Meetings regarding REMS or postmarketing requirements Meetings to discuss the overall development program for products granted breakthrough therapy designation
Type C Meetings	Type C meetings are basically a “catch all” category	Meeting concerning the development and review of a product that does not fall within the scope of Types A or B.

What is the content of the meeting request?

Content of the meeting request is as follows:

1. Product name
2. Application number (if applicable)
3. Chemical name and structure
4. Proposed indication(s) or context of product development
5. Meeting type
6. Brief statement of the purpose and objectives of the meeting
7. Proposed agenda
8. List of proposed questions, grouped by discipline
9. List of all individuals who will be in attendance at the requested meeting (including name, title, and affiliations)
10. List of FDA staff, if known, or disciplines asked to participate in the requested meeting
11. Suggested dates and times for the meeting (must be within or beyond the appropriate time frame of the meeting type being requested)
12. Proposed format of the meeting (written response, face-to-face, etc.)
13. Approximate date the meeting package will be sent

When will FDA respond to a meeting request?

Formal meetings are scheduled within the time frames below:

TYPE OF THE MEETING	A	B	C
FDA decision to grant /deny	14 days	21 days	21 days
Meeting schedule	30 days	60 days	75 days
Meeting package submission to FDA	With meeting request	30 days	30 days

Can a meeting with FDA be rescheduled or canceled?

In some circumstances the sponsor has to reschedule or cancel a planned meeting with FDA. In that case, the sponsor has to inform the Agency as soon as possible and request another meeting if they wish to reschedule it.

Why do I need a meeting package?

The purpose of the meeting package is to provide enough product information to the FDA, so that the agency can respond to the sponsor's questions.

Where should the meeting package be sent to?

The meeting package should be sent to the appropriate review division within either CBER or CDER. The meeting package should identify the date, time, and subject of the meeting.

How many copies of the meeting package are needed by FDA?

The number of copies of the meeting package vary from meeting to meeting. The responsible point of contact in the review division will advise on the number of copies needed for the meeting attendees.

What is the content of the meeting package?

The content of the meeting is as follows:

- Product name and application number
- Chemical name and structure
- Proposed indication
- Dosage form, route of administration, and dosing regimen
- List of all individuals who will be attending the meeting
- Background section, including:
 - Brief history of the development program and the events leading up to the meeting
 - Status of product development
- Brief statement summarizing the meeting purpose
- Proposed agenda
- List of the final questions to FDA
- Data to support discussion organized by discipline and question

How are FDA formal meetings conducted?

Formal meetings with FDA are chaired by FDA Regulatory Project Managers (RPM). The meetings start with an introduction and a statement of the agenda. Normally, sponsors do not need to prepare presentations because the information to be discussed should be in the meeting package. However, if a sponsor wants to make a presentation, it should be discussed with the FDA project manager before the meeting date. FDA won't extend the length of the meeting to accommodate sponsor's presentation. Additionally, FDA doesn't accept and won't comment on new data or information that hasn't been included in the meeting package.

At the end of the meeting, FDA project manager summarizes the important discussion points, agreements, clarifications, and action items to ensure that there is a mutual understanding of the meeting outcomes between FDA and sponsor. FDA issues the official meeting minutes within 30 days after the meeting.

Can I dispute the FDA meeting minutes?

Sponsor can ask additional clarification regarding the FDA meeting minutes and should notify the Agency in writing concerning the specific disagreements. FDA will consider the sponsor's concerns, and will generate an addendum to the official meeting minutes in case of agreement.

Best Practices for Meeting Request

- 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>

Best practices for successful formal meeting with FDA

- Work with RPM* to establish an agreeable agenda and list of questions.
- Notify the RPM of any last minute changes such as:
 - List of attendees
 - Need for audio/visual equipment
 - Meeting format
- Provide any meeting hand-outs and/or slides, if possible before the meeting.
- Schedule Meetings to discuss specific issues:
 - Submit focused questions.
 - Avoid open ended questions.
 - Avoid hypothetical situations that are difficult to address.
- Do not schedule meetings to pre-review data.
- Utilize FDA guidance documents to the fullest.

* RPM= Regulatory Project Manager

Global Regulatory Partners has been working with the Agency for more than 25 years and has a proven track record of helping many companies achieve successful meetings with FDA. To learn more about how we can help you with your FDA meetings, contact us today at info@globalregulatorypartners.com or call us at +1 781-672-4200.

REFERENCES

FDA Guidance for Industry Formal Meetings Between the FDA and Sponsors or Applicants