FDA Meeting Types with CDER and CBER for Biosimilar Products

Why Meet with FDA?

For biosimilar developers, early and successful interactions with FDA are crucial to ensuring that the health authority is well-informed and supports your planned development path. Meeting with FDA provides sponsors the opportunity to get feedback on critical development issues, which can reduce costs, regulatory risk, and time to approval. To meet with FDA, you will need to decide on your preferred format for the meeting (face-to-face, teleconference, or written responses), and submit a formal meeting request accompanied with or followed closely by an informational package. Once the FDA has reviewed your meeting request, they will determine whether to grant the meeting and determine the meeting format.

FDA GUIDANCE ON MEETINGS

The FDA has issued formal guidance on this entire process, Formal Meetings Between the FDA and Sponsors or Applicants of BsUFA Products Guidance for Industry.

Types of FDA Meetings for Biosimilar Products

Below is a summary of the different types of meetings under BsUFA for biosimilar products, when they apply, examples of, and the timing parameters of each meeting type.

BIOSIMILAR INITIAL ADVISORY (BIA) MEETING

Examples of BIA Meetings:

- The BIA meeting is similar to a pre-IND meeting and is used to assess the feasibility of the biosimilar 351(k) pathway
- The FDA expects preliminary comparative analytical data of at least one lot of the biosimilar and reference products tested
- Extensive analysis is not conducted at this meeting

Timing parameters of BIA Meetings:

- Day 0: Submit meeting request and briefing package
- Day 75: Meeting held with FDA

*Does not incur the initial biosimilar product development fee

BPD TYPE 1 MEETINGS: **URGENT SITUATIONS**

Examples of Type 2 Meetings:

- Analogous to a PDUFA Type A Meeting for stalled programs
- Meetings to discuss important safety concerns
- Dispute resolutions over regulatory actions such as an incomplete response letter or a refuse-to-file

Timing Parameters of Type 1 Meetings

- Day 0: Submit meeting request and briefing package
- Within 30 days: Meeting held with FDA

* Incurs the initial biosimilar product development fee

BPD TYPE 2 MEETINGS: **SPECIFIC TOPICS WITH LESS URGENCY**

Examples of Type 2 Meetings:

- Analogous to a PDUFA Type C meeting to discuss any specific issues in an ongoing program
- Meetings for discussing specific issues (e.g., processing critical quality attributes or non-clinical or clinical study design and endpoints)
- Does not include review of a full study report

Timing Parameters of Type 2 Meetings:

- Day 0: Submit meeting request and briefing package
- Within 90 days: Meeting held with FDA

*Incurs the initial biosimilar product development fee

BPD TYPE 3 MEETINGS: **IN-DEPTH DATA REVIEW**

Examples of Type 3 Meetings:

- Unique to BsUFA; an in-depth review of all analytical similarity data, with a preliminary evaluation of the analytical similarity exercise performed by the FDA
- Level of analytical data provided should be similar to what the sponsor intends to submit in a 351(k) BLA
- FDA expects an update on the product development plan
- Briefing package(s) should be well organized to serve as a template for the submission of the 351(k) BLA

Timing Parameters of Type 3 Meetings:

- Day 0: Submit meeting request and briefing package
- Day 120: FDA accepts or denies meeting, specifies meeting format, and schedules date

* Incurs the initial biosimilar product development fee

BPD TYPE 4 MEETINGS: **SPECIFIC DEVELOPMENT PROGRAM MILESTONES**

Examples of Type 4 Meetings:

- Analogous to a pre-NDA or pre-BLA PDUFA meeting to discuss the format and content of the planned submission
- Be clear on studies that will be used to support the demonstration of biosimilarity
- Identify ongoing studies

Timing Parameters of Type 4 Meetings

- Day 0: Submit meeting request and briefing package
- Day 60: FDA accepts or denies meeting, specifies meeting format, and schedules date

Ensure a Successful Regulatory Agency Interaction

Developing a strong relationship with FDA is key to ensuring that the Agency is knowledgeable about your product and supports its development pathway. To give you an advantage, Veristat's team of regulatory experts are adept at preparing for, attending, and facilitating meetings with FDA.

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