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FDA Finalizes Guidance For Formal Meetings Between the FDA and Biosimilars Applicants

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On November 17, 2015, the FDA finalized a guidance document, that was first issued as a draft in March 2013, regarding formal meetings between the FDA and biosimilars applicants. Because meetings with biosimilars applicants are critical points in the regulatory and development process, the FDA reiterated the importance of having efficient, consistent procedures for the timely and effective conduct of such meetings. According to the FDA, this guidance document is intended to provide consistent procedures that will promote well-managed meetings, and ensure that such meetings are scheduled within a reasonable time, conducted efficiently, and documented appropriately.

The final guidance does not differ significantly from the draft of 2013, and maps out the five types of meetings that a biosimilars applicant can request with the FDA.

Biosimilar Initial Advisory meeting:

A Biosimilar Initial Advisory meeting is an initial assessment limited to a general discussion regarding whether approval as a biosimilar is feasible for a particular product, and, if so, to general advice on the expected content of the development program. This meeting type does not include substantive review of summary data or full study reports. However, preliminary comparative analytical similarity data from at least one lot of the proposed biosimilar biological product compared to the U.S.-licensed reference product should be provided in the meeting package. The analytical similarity data should be sufficient to enable the FDA to make a preliminary determination as to whether licensure may be feasible for a particular product, and to provide meaningful advice.

BPD Type 1 meeting:

A Biosimilar Biological Product Development (BPD) Type 1 meeting is a meeting that is necessary for an otherwise stalled BPD program to proceed. Examples of a BPD Type 1 meeting include: meetings to discuss clinical holds; special protocol assessment meetings; meetings to discuss an important safety issue; and dispute resolution meetings with the FDA.

BPD Type 2 meeting:

A BPD Type 2 meeting is a meeting to discuss a specific issue (e.g., proposed study design or endpoints) or questions where the FDA will provide targeted advice regarding an ongoing BPD program. This meeting type can include substantive review of summary data, but does not include review of full study reports.

BPD Type 3 meeting:

A BPD Type 3 meeting is an in-depth data review and advice meeting regarding an ongoing BPD program. This meeting type includes substantive review of full study reports or an extensive data package (e.g., detailed and robust analytical similarity data), FDA advice regarding the similarity between the proposed biosimilar biological product and the reference product based on a comprehensive data package, and FDA advice regarding the need for additional studies, including design and analysis, based on a comprehensive data package.

BPD Type 4 meeting:

A BPD Type 4 meeting is a meeting to discuss the format and content of a biosimilar biological product application or supplement to be submitted under section 351(k) of the PHS Act. Although the proposed content of the application will be discussed, this meeting type does not include substantive review of summary data or full study reports.

While applicants are not required to request meetings in sequential order (i.e., Biosimilar Initial Advisory meeting, BPD Type 2, BPD Type 3, then BPD Type 4), an applicant must pay a biosimilar biological product development fee (BPD fee) in order to participate in the FDA's BPD program and receive a BPD Type 1, 2, 3, or 4 meeting for a product. The meeting type requested depends on the stage of the development program and/or the advice being sought. Although the FDA would most likely grant one Biosimilar Initial Advisory meeting and BPD Type 4 meeting for a particular biosimilar product, applicants can request, as appropriate, as many BPD Type 2 and Type 3 meetings as needed to support ongoing development of a biosimilar product.

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