

of the PHSA may be feasible for a particular product, and, if so, a general advice on the expected content of the development program. This meeting type does not include any meeting that involves a substantive review of summary data or full study reports. However, preliminary comparative analytical similarity data should be provided with the meeting request to enable the FDA to make the initial determination as to whether licensure under Section 351(k) of the PHSA may be feasible for a particular product and to provide meaningful advice. An overview of the proposed development program also should be supplied.

### 3.3.2 Biosimilar biological product development (BPD) Type 1 meeting

A 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 the following:

- Meetings to discuss clinical holds in which a response to hold issues has been submitted, but the FDA and the sponsor or applicant agree that the development is stalled, and a new path forward should be discussed
- Special protocol assessment meetings that are requested by sponsors or applicants after the receipt of the FDA evaluation of protocols under the special protocol evaluation procedures as described in Section VI of the Biosimilar User Fee Act of 2012 (BsUFA) goals letter
- Meetings to discuss an important safety issue, when such an issue is identified, and the FDA and the sponsor or applicant agree that the matter should be discussed
- Dispute resolution meetings as described in 21 Code of Federal Regulations (CFR) 10.75 and 312.48 and in Section 102 IV of the BsUFA goals letter and the draft guidance for industry and review staff (Formal Dispute Resolution: Appeals Above the Division Level 7, lines 104–105)

### 3.3.3 BPD Type 2 meeting

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

### 3.3.4 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 a