The Q&A format is intended to promote transparency and facilitate development programs for proposed biosimilar products by addressing questions that may arise in the early stages of development. In addition, these Q&As respond to questions the Agency has received from prospective BLA and NDA applicants regarding the appropriate statutory authority under which certain products will be regulated. The FDA intends to update this guidance to include additional Q&As as appropriate. Table 3.1 describes the status of the draft guidance Q&As provided in this guidance and the final guidance Q&As that are included in the guidance on *Biosimilars: Questions and Answers Regarding Implementation of the Biologics Price Competition and Innovation Act of 2009.* The FDA has maintained the original numbering of the Q&As used in the February 2012 draft guidance. Q&As that have been finalized appear in the final guidance, and the omission of these Q&As from this revised draft guidance is marked by several asterisks between nonconsecutively numbered Q&As.

3.12.2 Biosimilarity or interchangeability

Q. I.1: Whom should a sponsor contact with questions about its proposed biosimilar development program?

A. I.1: If the reference product for a proposed biosimilar product is regulated by the Center for Drug Evaluation and Research (CDER), contact the Therapeutic Biologics and Biosimilars Team (TBBT) in CDER's Office of New Drugs at 301-796-0700.

If the reference product for a proposed biosimilar product is regulated by the Center for Biologics Evaluation and Research (CBER), contact the Office of Communication, Outreach and Development (OCOD) at 800-835-4709 or 240-402-7800 or by email to ocod@fda.hhs.gov.

For general questions related to the FDA's implementation of the BPCI Act, contact Sandra Benton in CDER's Office of Medical Policy at 301-796-2500.

Q. I.2: When should a sponsor request a meeting with the FDA to discuss their proposed biosimilar development program, and what data and information should a sponsor provide to the FDA as background for this meeting?

A. I.2: Sponsors can request meetings at any time point in their development program. The FDA recommends that sponsors refer to the draft guidance for industry titled *Formal Meetings between the FDA and Biosimilar Biological Product Sponsors or Applicants* to determine the most appropriate meeting type to request. This draft guidance describes the different meeting types intended to facilitate biosimilar development programs in accordance with the Biosimilar User Fee Act of 2012 (BsUFA) and the criteria/data needed to support the request. The type of meeting granted will depend on the stage