guidance for industry on Biosimilars: Questions and Answers Regarding Implementation of the Biologics Price Competition and Innovation Act of 2009 for additional information on extrapolation under the BPCI Act. If the submitted scientific justification for extrapolation under the BPCI Act is inadequate, a biosimilar applicant must submit appropriate data to fulfill applicable PREA requirements.

- Lack of adequate pediatric information in reference product labeling
  - If the labeling for the reference product does not contain adequate pediatric information for one or more indications for which a biosimilar applicant seeks licensure in adults, and applicable PREA requirements were deferred for the reference product for those indications, a biosimilar applicant should request a deferral of PREA requirements for those indications.

If PREA requirements were waived for the reference product sponsor for those indications, and if the biosimilar applicant believes that its proposed product meets the requirements for a full or partial waiver of PREA requirements under section 505B(a)(4) of the FD&C Act, the biosimilar applicant should request a full or partial waiver for those indications.

If a biosimilar applicant believes that none of the situations described above applies to its proposed product, the applicant should contact the FDA for further information.

Q. I.17: When should a proposed biosimilar product applicant submit an initial pediatric study plan (PSP)? [New]

A. I.17 (Proposed Answer): Section 505B(e) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by Section 506 of the Food and Drug Administration Safety and Innovation Act (FDA SIA), requires applicants subject to the Pediatric Research Equity Act (PREA) to submit an initial pediatric study plan (PSP) no later than 60 calendar days after the date of an end-of-Phase 2 (EOP2) meeting, or at another time agreed upon by the FDA and the applicant. This provision of FDA SIA has an effective date of January 5, 2013. The FDA has issued draft guidance on the PSP process, including the timing of PSP submission, as required by section 505B(e)(7) of the FD&C Act.

Sections 505B(e)(2)(C) and 505B(e)(3) of the FD&C Act set forth a process for reaching an agreement between an applicant and the FDA on an initial PSP that lasts up to 210 days. Given the potential length of this process, and in the absence of an EOP2 meeting for a proposed biosimilar product, the FDA recommends that if a sponsor has not already initiated a comparative clinical study intended to address the