

that certain biological products are safe, pure, and potent in order to facilitate biosimilar development programs and submission of 351(k) applications. We note, however, that the publicly available information posted by the FDA in this context does not necessarily include all of the information that would otherwise be disclosable in response to a Freedom of Information Act request.

*Q. I.14:* Can an applicant obtain a determination of interchangeability between its proposed product and the reference product in an original 351(k) application?

*A. I.14 (Proposed Answer):* Yes. Under the BPCI Act, the FDA can make a determination of interchangeability in a 351(k) application or any supplement to a 351(k) application. An interchangeable product must be shown to be biosimilar to the reference product and meet the other standards described in section 351(k)(4) of the PHS Act. At this time, it would be difficult as a scientific matter for a prospective biosimilar applicant to establish interchangeability in an original 351(k) application given the statutory standard for interchangeability and the sequential nature of that assessment. The FDA is continuing to consider the type of information sufficient to enable the FDA to determine that a biological product is interchangeable with the reference product.

*Q. I.15:* Is a pediatric assessment under the Pediatric Research Equity Act (PREA) required for a proposed biosimilar product?

*A. I.15:* Under the Pediatric Research Equity Act (PREA) (section 505B of the FD&C Act), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain a pediatric assessment to support dosing, safety, and effectiveness of the product for the claimed indication unless this requirement is waived, deferred, or inapplicable.

Section 505B(n) of the FD&C Act, added by section 7002(d)(2) of the Affordable Care Act, provides that a biosimilar product that has not been determined to be interchangeable with the reference product is considered to have a “new active ingredient” for purposes of PREA, and pediatric assessment is required unless waived or deferred. Under the statute, an interchangeable product is not considered to have a “new active ingredient” for purposes of PREA. Therefore, if a biological product is determined to be interchangeable with the reference product, PREA would not be triggered, and a pediatric assessment of the interchangeable product would not be required. However, if an applicant first seeks licensure of its proposed product as a non-interchangeable biosimilar product and intends to seek subsequently licensure of the product as interchangeable, the applicant still must address