

requirements under section 351(k)(2)(A)(i)(I)(cc) of the Public Health Service (PHS) Act, the sponsor should submit an initial PSP as soon as feasible, but no later than 210 days before initiating such a study. This is intended to provide adequate time to reach an agreement with the FDA on the initial PSP before the study is initiated. Depending on the details of the clinical program, it may be appropriate to submit an initial PSP earlier in development. The FDA encourages the sponsor to meet with the FDA to discuss the details of the planned development program before submission of the initial PSP.

The initial PSP must include an outline of the pediatric study or studies that a sponsor plans to conduct (including, to the extent practicable, study objectives and design, age groups, relevant endpoints, and statistical approach); any request for a deferral, partial waiver, or full waiver, if applicable, along with any supporting documentation; and should also include any previously negotiated pediatric plans with other regulatory authorities. For additional guidance on submission of the PSP, including a PSP Template, please refer to <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/ucm049867.htm>. After the initial PSP is submitted, a sponsor must work with the FDA to reach timely agreement on the plan, as required by section 505B(e)(2)–(3) of the FD&C Act. It should be noted that requested deferrals or waivers in the initial PSP will not be formally granted or denied until the product is licensed.

*Q. I.18:* For biological products intended to be injected, how can an applicant demonstrate that its proposed biosimilar product has the same “dosage form” as the reference product? [New]

*A. I.18 (Proposed Answer):* Under section 351(k)(2)(A)(i)(IV) of the PHS Act, an applicant must demonstrate that the dosage form of the proposed biosimilar or interchangeable product is the same as that of the reference product. For purposes of implementing this statutory provision, the FDA considers the dosage form to be the physical manifestation containing the active and inactive ingredients that deliver a dose of the drug product. In the context of proposed biosimilar products intended to be injected, the FDA considers, for example, “injection” (e.g., a solution) to be a different dosage form from “for injection” (e.g., lyophilized powder). Thus, if the reference product is an “injection,” an applicant could not obtain licensure of a proposed biosimilar “for injection” even if the applicant demonstrated that the proposed biosimilar product, when constituted or reconstituted, could meet the other requirements for an application for a proposed biosimilar product.

For purposes of section 351(k)(2)(A)(i)(IV) of the PHS Act, the FDA also considers emulsions and suspensions of