of product development and whether the information submitted in the meeting package meets the criteria for the kind of meeting.

See the FDA's draft guidance for industry on *Formal Meetings between the FDA and Biosimilar Biological Product Sponsors or Applicants*: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM345649.pdf.

See the FDA's BsUFA website: http://www.fda.gov/ForIndustry/UserFees/BiosimilarUserFeeActBsUFA/defaul.htm.

Q. I.3: Can a proposed biosimilar product have a different formulation than the reference product?

A. I.3: Yes, differences between the formulation of a proposed product and the reference product may be acceptable. A 351(k) application must contain information demonstrating that the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components. In addition, an applicant would need to show that there are no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency. It may be possible, for example, for a proposed product formulated without human serum albumin to demonstrate biosimilarity to a reference product formulated with human serum albumin. For more information about FDA's current thinking on the interpretation of the statutory standard for biosimilarity, see the FDA's draft guidances for industry on *Quality Considerations in Demonstrating Biosimilarity of a Therapeutic Protein Product to a Reference Product* and *Scientific Considerations in Demonstrating Biosimilarity to a Reference Product*.

Q. I.4: Can a proposed biosimilar product have a delivery device or container closure system that is different from its reference product?

A. I.4: Yes, some design differences in the delivery device or container closure system used with the proposed biosimilar product may be acceptable. It may be possible, for example, for an applicant to obtain licensure of a proposed biosimilar product in a pre-filled syringe or in an auto-injector device (which are considered the same dosage form), even if the reference product is licensed in a vial presentation, provided that the proposed product meets the statutory standard for biosimilarity and adequate performance data for the delivery device or container closure system are provided. For a proposed biosimilar product in a different delivery device or container closure system, the presentation must be shown to be compatible for use with the final formulation of the biological product through appropriate studies, including, for example,