products intended to be injected to be distinct dosage forms. Liposomes, lipid complexes, and products with extended-release characteristics present special scenarios due to their unique composition, and prospective applicants seeking further information should contact the FDA.

It should be noted, however, that this interpretation regarding the same dosage form is for purposes of section 351(k)(2)(A)(i)(IV) of the PHS Act only. For example, this interpretation should not be cited by applicants seeking approval of a new drug application under section 505(c) of the FD&C Act or licensure of a BLA under section 351(a) of the PHS Act for purposes of determining whether separate applications should be submitted and assessed separate fees for different dosage forms. For more information about the prescription drug user fee bundling policy, see the FDA's guidance for industry on *Submitting Separate Marketing Applications and Clinical Data for Purposes of Assessing User Fees*, available at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM079320.pdf.

Q. I.19: If a non-U.S.-licensed product is proposed for importation and use in the U.S. in a clinical investigation intended to support a proposed biosimilar development program (e.g., a bridging clinical PK and/or PD study), is a separate IND required for the non-U.S.-licensed product? [New]

A. I.19 (Proposed Answer): No, a sponsor may submit a single IND for its proposed biosimilar development program, and may submit information supporting the proposed clinical investigation with the non-U.S.-licensed comparator product under the same IND. This scenario may occur, for example, if a sponsor seeks to use data from a clinical study comparing its proposed biosimilar product to a non-U.S.-licensed product to address, in part, the requirements under section 351(k)(2)(A) of the PHS Act, and proposes to conduct a clinical PK and/or PD study in the U.S. with all three products (i.e., the proposed biosimilar product, the U.S.-licensed reference product, and the non-U.S.-licensed product) to support establishment of a bridge to the U.S.-licensed reference product and scientific justification for the relevance of these comparative data to an assessment of biosimilarity.

A non-U.S.-licensed comparator product is considered an investigational new drug in the United States, and thus would require an IND for importation and use in the United States (see 21 CFR 312.110(a)). If a sponsor intends to conduct a clinical investigation in the United States using a non-U.S.-licensed comparator product, the IND requirements in 21 CFR part 312 also would apply to this product (see, e.g., 21 CFR 312.2).

With respect to chemistry, manufacturing, and controls (CMC) information, a sponsor should submit to the IND as