product to be licensed under 351(k) of the PHSA based on less than a full complement of product-specific preclinical and clinical data.

4.2.1 The FDA defines biosimilars or biosimilarity

- The biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components.
- There are no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency of the product.

4.2.2 What reference product means

- The single biological product, licensed under Section 351(a) of the PHSA, against which a biological product is evaluated in an application submitted under Section 351(k) of the PHSA.

Note: A biological product, in a 351(k) application, may not be evaluated against more than one reference product.

4.2.3 What interchangeable or interchangeability means

- The biological product is biosimilar to the reference product.
- It can be expected to produce the same clinical result as the reference product in any given patient.
- For a product that is administered more than once to an individual, the risk in terms of safety or diminished efficacy of alternating or switching between use of the product and its reference product is not greater than the risk of using the reference product without such alternation or switch.

Note: The interchangeable product may be substituted for the reference product without the intervention of the healthcare provider who prescribed the reference product.

4.2.4 351(k) application content

A 351(k) application must include information demonstrating the following:

- The biological product is biosimilar to a reference product.
- The biological product utilizes the same MOAs for the proposed conditions of use—but only to the extent that the mechanisms are known for the reference product.
- The biological product's conditions of use proposed in labeling have been previously approved for the reference product.