biological product (an already-licensed FDA biological product). Biosimilar and interchangeable biological products licensed under Section 351(k) of the PHSA will be listed under the reference product to which biosimilarity or interchangeability was demonstrated. Separate lists for those biological products regulated by the CDER and the CBER will be updated periodically.

2.2.2 Regulatory guidance

The FDA has struggled coming up with final guidelines for the development of biosimilars starting with the first installment in 2015 (Table 2.1).

2.2.3 The 351(k) Route

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

- The biological product is biosimilar to a reference product.
- It utilizes the same mechanism(s) of action for the proposed condition(s) of use—only to the extent known for the reference product.

Table 2.1 FDA Guidance on Biosimilars

Category	Title	Type	Date
Procedural; biosimilarity	Reference Product Exclusivity for Biological Products Filed Under Section 351(a) of the PHS Act	Draft guidance	08/04/14
Biosimilarity	Scientific Considerations in Demonstrating Biosimilarity to a Reference Product	Final guidance	04/28/15
Biosimilarity	Quality Considerations in Demonstrating Biosimilarity of a Therapeutic Protein Product to a Reference Product	Final guidance	04/28/15
Biosimilars	Biosimilars: Questions and Answers Regarding Implementation of the Biologics Price Competition and Innovation Act of 2009 Guidance for Industry	Final guidance	04/28/15
Biosimilarity	Biosimilars: Additional Questions and Answers Regarding Implementation of the Biologics Price Competition and Innovation Act of 2009	Draft guidance	05/12/15
Biosimilarity; procedural	Formal Meetings Between the FDA and Biosimilar Biological Product Sponsors or Applicants	Final guidance	11/17/15
Biosimilarity	Clinical Pharmacology Data to Support a Demonstration of Biosimilarity to a Reference Product	Final guidance	12/28/16
Biosimilars naming	Nonproprietary Naming Guidance	Final guidance	01/12/2017
Biosimilars	Considerations in Demonstrating Interchangeability with a Reference Product Guidance for Industry	Draft guidance	01/17/17
Biosimilars	Statistical Approaches to Evaluate Analytical Similarity	Draft guidance	09/21/17

Source: https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm290967.htm