

# Update: Biosimilar Program in the U.S.

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# Biosimilars Program

- As of April 1, 2018, 63 programs were enrolled in the Biosimilar Product Development (BPD) Program. CDER has received meeting requests to discuss the development of biosimilars for 31 different reference products.
- Since program inception and as of April 1, 2018, 12 companies have publicly announced submission of 23 351(k) BLAs to FDA.
- As of April 1, 2018, nine 351(k) BLAs for biosimilar products have been approved.
  - Zarxio (filgrastim-sndz)
  - Erelzi (etanercept-szzs)
  - Renflexis (infliximab-abda)
  - Mvasi (bevacizumab-awwb)
  - Ixifi (infliximab-qbtx)
  - Inflectra (infliximab-dyyb)
  - Amjetiva (adalimumab-atto)
  - Cyltezo (adalimumab-adbm)
  - Ogivri (trastuzumab-dkst)

# FDA Biosimilars Guidance



1. **Scientific Considerations in Demonstrating Biosimilarity to a Reference Product (final, 2015)**
2. **Quality Considerations in Demonstrating Biosimilarity to a Reference Protein Product (final, 2015)**
3. **Biosimilars: Questions and Answers Regarding Implementation of the Biologics Price Competition and Innovation Act of 2009 (final, 2015)**
4. **Formal Meetings Between the FDA and Biosimilar Biological Product Sponsors or Applicants (final, 2015)**
5. **Clinical Pharmacology Data to Support a Demonstration of Biosimilarity to a Reference Product (final, 2016)**
6. **Nonproprietary Naming of Biological Products (final, 2017)**
7. **Best Practices for Communication Between IND Sponsors and FDA During Drug Development [to apply to communications between IND sponsors and FDA during biosimilar biological product development] (final, 2017)**
8. **Biosimilars: Additional Questions and Answers Regarding Implementation of the Biologics Price Competition and Innovation Act of 2009 (draft, 2015)**
9. **Labeling for Biosimilar Products (draft, 2016)**
10. **Considerations in Demonstrating Interchangeability With a Reference Product (draft, 2017)**
11. **Statistical Approaches to Evaluate Analytical Similarity (draft, 2017)**

# Development of Future Guidance



- FDA has committed to publish draft, revised draft, or final guidance describing the following:
  - *Statistical Approaches to Evaluate Analytical Similarity* (draft guidance published September 2017; revised draft or final guidance by 5/21/19)
  - *Considerations in Demonstrating Interchangeability With a Reference Product* (draft guidance published January 2017; revised draft or final guidance by 5/19/19)
  - *Labeling for Biosimilar Biological Products* (draft guidance published March 2016; revised draft or final guidance by 5/31/19)
  - *Formal Meetings Between the FDA and Biosimilar Biological Product Sponsors or Applicants* (final guidance published November 2015; revised draft by 9/30/18)
  - *Good Review Management Practices* (revised draft by 9/30/18)
  - Processes and further considerations related to post-approval manufacturing changes for biosimilar biological products (draft guidance by 3/31/19)

# International Activities



- FDA-EMA-Health Canada-PMDA biosimilars cluster
  - Supporting an efficient global market for biosimilars entails sharing regulatory experience across national boundaries to support product development
  - Partnerships can facilitate global economies of scale in biosimilar development programs
- Supporting other NRAs through FDA's Office of International Programs

# Biosimilars: FDA Strategic Priority



- **FDA's 2018 Strategic Policy Roadmap** announced FDA's plan to launch a comprehensive program to encourage biosimilar competition.
- **Goal:** to help address the high cost of medicines through the development of science-based policies that can improve competition, access, and the opportunity for patients to benefit from safe and effective, and lower cost biosimilar alternatives.
  - Examining biosimilar program to better integrate policy and review functions that can provide greater scientific and regulatory clarity for sponsors, and greater efficiencies in the review of biosimilar and interchangeable applications.
  - Evaluating development of information resources and tools that can assist biosimilar sponsors in developing high quality biosimilar and interchangeable products using state of the art analytical techniques.
  - Modernizing regulatory policy to accommodate new scientific tools that can better enable comparison between biosimilars and reference products that may reduce the need for certain clinical studies.

# Education & Outreach Campaign for Biosimilars



- Launched by FDA in October 2017
- Goals of this initiative are to increase:
  - Understanding of biologics, reference products, biosimilars and interchangeable products.
  - Awareness of FDA's role in the biosimilar and interchangeable approval process.
  - Knowledge of the data and information FDA reviews/requires to determine biosimilarity and interchangeability.
  - Knowledge about the prescribing of biosimilar and interchangeable products.
- FDA offers a variety of patient and prescriber outreach materials, including graphics, drop-in content, and social media messages, to help promote understanding of biosimilars and interchangeable products.

For more information, go to  
[www.fda.gov/biosimilars](http://www.fda.gov/biosimilars)