# FDA's Biosimilars Action Plan

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# Balancing Innovation and Competition

- FDA recognizes both our important role in helping to ensure that the U.S. remains a driving force in medical innovation, as well as the importance of robust and timely competition to enhance patient access and reduce cost burdens on patients and our health care system.
- The FDA has and will continue to play a critical role in facilitating increased access to biosimilars.
  - To date, twelve 351(k) BLAs for biosimilar products have been approved under BPCI Act authority.
  - By increasing treatment options, biosimilars can enhance competition in the market for biological products without reducing incentives to innovate.
  - Availability of biosimilar and interchangeable products that meet the FDA's robust approval standards will improve access to biological products through lower treatment costs.
- FDA standards for evaluating a proposed biosimilar continue to incorporate new tools and state of the art techniques to demonstrate biosimilarity and interchangeability.

# Background

- BsUFA II Commitments October 2017
  - Advancing development of biosimilars through further clarification of the 351(k) regulatory pathway (commitments for FDA to issue guidance for industry)
  - Enhancing capacity for biosimilar regulations and guidance development, reviewer training and timely communication
    - strengthen staff capacity to develop new regulations and guidance, develop or revise MaPPs, SOPPs, and review templates, deliver timely communication to the public, deliver information concerning the date of first licensure and the reference product exclusivity, and update the Purple Book
- FDA released the Biosimilars Action Plan (BAP) July, 2018 to provide information about the key actions the Agency is taking to encourage innovation and competition among biologics and the development of biosimilars.
  - The BAP is a dynamic plan that builds on the Agency's progress in implementing the approval pathway for biosimilar and interchangeable products.
  - https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm613761.pdf

# Key Goals of the Biosimilars Action Plan (BAP)

1. Improving the efficiency of the biosimilar and interchangeable product development and approval process
2. Maximizing scientific and regulatory clarity for the biosimilar product development community
3. Developing effective communications to improve understanding of biosimilars among patients, clinicians and payors
4. Supporting market competition by reducing gaming of FDA requirements or other attempts to unfairly delay competition

# Goal #1 – Planned Deliverables:

- **Improving the efficiency of the biosimilar and interchangeable product development and approval process**
  - Proposed transition of TBBS to the Office of Therapeutic Biologics and Biosimilars (OTBB)
  - Develop and implement Associate Director for Biosimilars positions in key scientific review discipline organizations
  - Develop application review templates specifically for 351(k) BLAs
  - Develop information resources and development tools that can assist biosimilar sponsors, including:
    - Develop an index of critical quality attributes for use in comparing proposed biosimilars to certain reference products
    - Develop and validate pharmacodynamic biomarkers tailored to biosimilar development, and *in silico* modeling and simulation, to evaluate pharmacokinetic and pharmacodynamic response versus clinical response relationships using existing clinical data
  - Engage in a public dialogue through a Part 15 hearing and opening a docket to request additional information from the public on what additional policy steps the FDA should consider as we seek to enhance the biosimilar program – *Held September 4, 2018*

# Goal #2 – Planned Deliverables:

- **Maximizing scientific and regulatory clarity for the biosimilar product development community**
  - Guidance development
    - Final or Revised Drug Guidance: Labeling for Biosimilar Products (*final guidance issued July, 2018)*
    - Final or Revised Draft Guidance: Reference Product Exclusivity for Biological Products Filed Under Section 351(a) of the PHS Act
    - Final or Revised Draft Guidance: Implementation of the "Deemed to be a License" Provision of the Biologics Price Competition and Innovation Act of 2009
    - Final or Revised Draft Guidance: Considerations in Demonstrating Interchangeability with a Reference Product
    - Revised Draft Guidance: Statistical Approaches to Evaluate Analytical Similarity
      - Provide additional clarity and flexibility for product developers on analytical approaches to evaluate product structure and function to support a demonstration of biosimilarity
    - Draft Guidance: Processes and further considerations related to post-approval manufacturing changes for biosimilar biological products
    - Develop updated guidance to provide additional clarity to biosimilar applicants who seek approval for fewer than all conditions of use for which the reference product is licensed

# Goal #2 – Planned Deliverables Continued:

- **Maximizing scientific and regulatory clarity for the biosimilar product development community**
  - Develop a proposed rule on the interpretation of the definition of "biological product" in the BPCI Act
  - Evaluate FDA's regulations regarding the submission and review of BLAs to ensure that they account for current practices and authorities
  - Develop an enhanced Purple Book and continue commitment under the BsUFA II goals letter to publish information about newly approved or withdrawn BLAs and about reference product exclusivity determinations
  - Strengthen FDA's partnerships with regulatory authorities in Europe, Japan and Canada
    - Explore data sharing agreements that can give FDA better insights into biosimilars' real world safety and efficacy
    - Facilitate the increased use of non-U.S.-licensed comparator products in certain studies to support an application under section 351(k)
  - Advance efforts to use real-world evidence to support safety assessments and appropriate prescribing of biosimilars

# Goal #3 – Planned Deliverables:

- **Developing effective communications to improve understanding of biosimilars among patients, clinicians and payors**
  - Develop additional materials as part of FDA's Biosimilars Education and Outreach Campaign for patients and stakeholders
    - Develop a one-pager for patient audiences
    - Pursue video-format communications that can be used on social media for patient and other key audiences
  - Development of educational materials for health care prescribers and pharmacists
    - Pursue development of educational curriculum for use in medical and pharmacy schools
    - Develop slide presentation for health care professionals that includes case studies of FDA reviews of biosimilar products
  - Engage healthcare professional and patient stakeholders
    - Participate in conferences and meetings
    - Provide technical support for communications materials, when appropriate
    - Engage in direct dialogue with stakeholders to seek input on identifying knowledge gaps and communication tools
    - Hold a webinar for CE credit that covers information related to the labeling for and prescribing of biosimilar and interchangeable products

# Goal #4 – Planned Deliverables:

- **Supporting market competition by reducing gaming of FDA requirements or other attempts to unfairly delay competition**
  - Clarify FDA's position on issues affecting reference product exclusivity
  - Evaluate whether firms are using FDA statutory or regulatory requirements to inappropriately delay approval of biosimilar or interchangeable competitors
    - Coordinate with FTC to address anti-competitive behavior
    - Work with legislators to address any loopholes that may effectively delay competition beyond the exclusivity periods envisioned by Congress
  - Address circumstances in which drug makers refuse to sell samples, or use any other anticompetitive strategies, to delay the entry of biosimilar or interchangeable development and competition

# Part 15 Hearing

- Held September 4, 2018
- FR Notice - https://www.federalregister.gov/documents/2018/07/25/2018-15859/facilitating-competition-and-innovation-in-the-biological-products-marketplace-public-hearing
- Comment period open until September 21, 1018
- Docket - https://www.regulations.gov/docket?D=FDA-2018-N-2689

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**Thank you for your attention.**

**For more information, go to**
**www.fda.gov/biosimilars**