FDA NEWS RELEASE

FDA Moves to Accelerate Biosimilar Development and Lower Drug Costs

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For Immediate Release:
October 29, 2025

The U.S. Food and Drug Administration (FDA) today announced significant action to make it faster and less costly to develop biosimilar medicines, which are lower-cost "generic" alternatives to biologic drugs that treat serious and chronic diseases.

In a new draft guidance (https://www.fda.gov/media/189366/download), the FDA proposes major updates to simplify biosimilarity studies and reduce unnecessary clinical testing. The agency through a separate initiative also plans to make it easier for biosimilars to be developed as interchangeable with brand-name biologics, helping patients and pharmacists choose lower-cost options more easily.

Expensive biologic medications make up only 5% of prescriptions in the U.S. but account for 51% of total drug spending as of 2024. FDA-approved biosimilars are as safe and effective as the branded drugs, yet their market share remains below 20%. To date, FDA has approved 76 biosimilars (https://www.fda.gov/drugs/biosimilars/biosimilar-product-information), corresponding to a small fraction of approved biologics. By contrast, there are more than 30,000 approved generics (https://www.fda.gov/drugs/generic-drugs/office-generic-drugs-2022-annual-report), exceeding the number of approved brand drugs. Only about 10% of biologic drugs expected to lose patent protection in the next decade currently have a biosimilar in development.

“Today’s announcement of biosimilar reform furthers President Trump’s directive (https://www.whitehouse.gov/presidential-actions/2025/04/lowering-drug-prices-by-once-again-putting-americans-first/) to lower drug prices for the American people,” **Health and Human Services Secretary Robert F. Kennedy Jr. said**. “Biologics treat many chronic diseases, but for too long, a burdensome approval process has kept patients from accessing more affordable biosimilars. This bold action by the FDA accelerates biosimilar development, drives market competition, expands patient options, and advances our mission to Make America Healthy Again.”

“Biosimilars are often far more affordable to patients and have the promise to significantly lower health care costs in America,” **said FDA Commissioner Marty Makary, M.D., M.P.H.** “By streamlining the biosimilar development process and helping advance interchangeability, we can achieve massive cost reductions for advanced treatments for cancer, autoimmune diseases, and rare disorders affecting millions of Americans.”

“Science continues to evolve, and the FDA remains committed to advancing common-sense policies that further promote efficient and effective biosimilar and interchangeable biosimilar development, without compromising safety and effectiveness,” **said George Tidmarsh, M.D., Ph.D., Director, FDA Center for Drug Evaluation and Research**.

Today’s new FDA draft guidance (https://www.fda.gov/media/189366/download), “Scientific Considerations in Demonstrating Biosimilarity to a Reference Product: Updated Recommendations for Assessing the Need for Comparative Efficacy Studies,” is based on the agency’s accrued data and experience since the first biosimilar was approved in 2015. Despite requiring 1-3 years and costing $24 million on average, comparative efficacy studies generally have low sensitivity compared to

many other analytical assessments. The FDA's new guidance reduces this unnecessary resource-intensive requirement for developers to conduct comparative human clinical studies, allowing them to rely instead on analytical testing to demonstrate product differences.

Currently, in some circumstances, developers perform “switching studies” for biosimilars licensed as interchangeable – a step not required for generic drugs. These additional studies can slow development and create public confusion about biosimilar safety. The FDA now generally does not recommend switching studies.

The approval pathway for biosimilars was established by Congress in 2010 through the Biologics Price Competition and Innovation Act (BPCIA) to promote competition in markets dominated by high-cost biologics. Since then, the FDA has approved 76 biosimilars (https://www.fda.gov/drugs/biosimilars/biosimilar-product-information) that provide Americans additional treatment options for conditions such as cancer, rheumatoid arthritis, diabetes, Crohn’s disease, and osteoporosis.

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With today’s action, the FDA aims to help more companies bring affordable, high-quality biosimilars to market and reduce costs for the American people.

See FACT SHEET: Bringing Lower-Cost Biosimilar Drugs to American Patients (/media/189382/download?attachment).

Media:
FDA Request for Comment (https://www.hhs.gov/request-for-comment-form/index.html?Agency=FDA)
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