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U.S. Food and Drug Administration (FDA) proposes to fast-track biosimilar approvals, cutting clinical trial requirements

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In a new draft guidance, the FDA proposes major updates to simplify biosimilarity studies and reduce unnecessary clinical testing.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, corresponding to a small fraction of approved biologics. By contrast, there are more than 30,000 approved generics, 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.

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.
As industries and authorities adjust to this change, Echa and industry experts will continue to monitor advances in this area.

Reference:

FDA Moves to Accelerate Biosimilar Development and Lower Drug Costs | FDA