

# The Nucleus: Life Sciences Regulation and Enforcement Updates

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## FDA Moves to Streamline Biosimilar Development: The Implications for Regulatory and IP Strategy

### Executive Summary

- **What's new:** The FDA issued updated guidance on the requirements for biosimilar sponsors seeking to use foreign comparator products in clinical studies. Most notably, the FDA has eliminated the default requirement for a three-way pharmacokinetic bridging study.
- **Why it matters:** The change lowers regulatory hurdles and could reduce some development costs by up to 50%, making it easier for biosimilars to come to market, which should spur competition in the run-up to the coming “patent cliff,” when patents on many blockbuster drugs will expire.
- **What to do next:** Biosimilar developers may want to revise their development strategies to lean more heavily on foreign comparators in clinical trials. Innovative companies may need to evolve their strategies for addressing biosimilar competition, adopting approaches that are increasingly similar to those they have traditionally used in response to generic entrants.

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The U.S. Food and Drug Administration (FDA)'s [March 2026 update to its biosimilar Q&A guidance](#) arrives at a critical inflection point for the biopharmaceutical sector, as the industry faces a looming “patent cliff” with more than \$200 billion in annual biologic revenues at risk due to patent expirations by 2030.

The FDA's revised guidance — which eliminates the requirement for a three-way pharmacokinetic (PK) bridging study between the proposed biosimilar, the U.S.-licensed reference product and the foreign comparator — is designed to lower regulatory hurdles, reduce development costs and facilitate earlier biosimilar market entry. These goals are becoming increasingly urgent as payers, providers and patients demand broader access to affordable biologic therapies.

For life sciences companies, this guidance not only signals a new regulatory paradigm but also creates fresh opportunities and challenges in global development planning, intellectual property (IP) strategy and competitive positioning.

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## Overview of the Guidance Update

The March 2026 revision to the FDA's biosimilar Q&A guidance fundamentally changes the requirements for sponsors seeking to use non-U.S.-licensed (foreign) comparator products in clinical studies for biosimilars. Most notably, the FDA has eliminated the default requirement for a three-way PK bridging study, which previously mandated direct comparison among the proposed biosimilar, the U.S.-licensed reference product and the foreign comparator. Under the new guidance, sponsors may now justify the relevance of clinical data generated with a foreign comparator through robust scientific rationale, advanced analytical data and, where appropriate, publicly available information.

This shift reflects the FDA's growing confidence in the power of analytical and PK data to establish biosimilarity, and it brings the U.S. regulatory framework into closer alignment with international standards, particularly those of the European Medicines Agency (EMA).

The FDA's update is not merely a technical adjustment; it is a strategic recalibration that builds on the agency's October 2025 draft guidance, which had already signaled that comparative efficacy studies would no longer be the default requirement for biosimilar approval. The cumulative effect is a streamlined clinical data package for biosimilar applications, which the FDA estimates could save developers up to 50% of PK study costs — potentially as much as \$20 million per program — by avoiding unnecessary bridging studies. See our November 4, 2025, client alert [“FDA Policy Changes Could Bring Some Biosimilars to Market Faster.”](#)

The FDA's updated guidance is emblematic of a broader regulatory trend: increasing reliance on comparative analytical studies as the primary evidence of biosimilarity. This shift is consistent with the agency's recent policy changes regarding interchangeability, where the focus has moved away from extensive clinical switching studies and toward robust in vitro analytical and functional data. The FDA now explicitly recognizes that, for highly purified therapeutic proteins, analytical and PK data can serve as a reliable surrogate for clinical efficacy and safety data. This position is supported by the agency's own experience, which has shown that clinical studies have rarely, if ever, detected issues not already identified analytically.

## Use of Foreign/Global Reference Products

The FDA's revised stance on the use of foreign comparators is a direct response to persistent industry concerns about the scientific, logistical and economic burdens imposed by the previous

bridging requirements. The new guidance acknowledges that, in most cases, foreign-licensed reference products — when sourced from jurisdictions that adhere to International Council for Harmonisation guidelines and supported by robust analytical data — are materially representative of their U.S. counterparts.

Most reference biologics are manufactured at a single site for global distribution. As a result, foreign and U.S. versions are analytically and functionally equivalent for the purposes of biosimilar development. For biosimilar sponsors, the ability to use a single reference product across multiple jurisdictions enables the design of global clinical programs that reduce duplication, accelerate timelines and facilitate simultaneous launches in the U.S., EU and other major markets.

This harmonization is particularly valuable given the increasing globalization of biosimilar development and the need to satisfy multiple regulatory bodies with a unified data package. The FDA's new approach closely mirrors the EMA's established practice of permitting analytical-only bridging in many cases, allowing sponsors to leverage a single development program for multiple regulatory submissions.

Logistical challenges have long plagued biosimilar developers, in particular, sourcing sufficient quantities of U.S.-licensed reference product for clinical studies. U.S. reference products are more expensive than their foreign counterparts and may not be as readily available due to the way pharmaceuticals are distributed in the U.S. versus other countries, making procurement both costly and complex. Ensuring access to recent, consistent batches, which is essential for supporting biosimilarity, is especially difficult for large, multicenter or global studies. In contrast, foreign-sourced product is often more readily available and less costly, making it a practical choice for sponsors seeking to optimize their development programs.

The cost implications of the new guidance are substantial. The prior requirement for three-way PK studies imposed significant direct costs — often \$1 million to \$2 million per study — and multiplied these costs across sponsors and jurisdictions. By allowing sponsors to avoid these expenses when scientific justification is provided, the FDA is enabling more efficient allocation of resources and accelerating the pace at which biosimilars can reach the market.

## Implications for IP Strategy and Competition

Any major regulatory change in this space also brings related intellectual property strategic considerations for both innovator and biosimilar manufacturers.

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For biosimilar developers, the elimination of the clinical PK bridging requirement for foreign reference products may postpone the need to defend against potential patent infringement claims. Even though biosimilar development is subject to the safe harbor (sometimes called the Bolar exemption), procuring large quantities of U.S.-licensed reference product for clinical studies can alert originator companies to impending biosimilar development, potentially triggering preemptive patent litigation or supply restrictions. By minimizing the use of U.S.-licensed reference product in clinical studies, biosimilar sponsors may be able to reduce the risk of such litigation, preserving strategic flexibility.

Moreover, the fact that data generated with foreign comparators can be leveraged to support regulatory submissions in multiple jurisdictions, may reduce the need for U.S.-specific studies that could expose sponsors to additional patent claims.

Limiting the use of U.S.-licensed product in development may also reduce the volume of data available to originator companies for challenging biosimilar applications, potentially narrowing the scope of litigation and facilitating earlier settlements.

While these changes may be helpful to biosimilar sponsors in moderately reducing IP litigation risk, this policy issue is not new and innovator companies have had time to prepare for more streamlined biosimilar development programs. Innovators have been strengthening IP strategies, lifecycle management and planning for increased biosimilar entry as the patent cliff approaches. With the regulatory barriers to biosimilar entry being lowered in recent years, originator companies are prepared to face a more rapid and globally coordinated wave of biosimilar competition. While originators are still able to rely on the same level of market exclusivity, regulatory streamlining of the biosimilar pathway intensifies the urgency to deploy robust lifecycle management tactics.

Innovators have strategies at their disposal, such as developing next-generation or “biobetter” formulations, expanding into new indications and securing additional patents on delivery devices, manufacturing processes or novel combinations to extend their commercial runway beyond the initial loss of exclusivity.

The increased reliance on analytical data and global harmonization also means that originators are preparing to take on biosimilar challenges not just in the U.S., but across all major markets simultaneously, requiring a more integrated and proactive approach to global IP defense and regulatory engagement. Furthermore, as biosimilar sponsors can now more easily source foreign reference product and avoid early detection by originator companies, and innovators may therefore have less advance notice of competitive threats, the need for innovators to have real-time market intelligence and rapid response capabilities is likely to increase.

Ultimately, the new FDA framework compels innovator biologics companies to continue to improve their lifecycle management playbooks, prioritize innovation and differentiation, and prepare for a more dynamic, competitive and cost-sensitive biologics marketplace.

## Conclusion

The FDA’s 2026 update to its biosimilar Q&A guidance will further facilitate biosimilar development in the U.S. For biosimilar companies, the new framework offers a clear mandate: Leverage global development efficiencies, rely on advanced analytical science and strategically manage IP risk to accelerate biosimilar market entry as the biologics patent cliff looms. For innovators, a focus on lifecycle management and rapid response to potential patent challenges remains as important, if not more so, than ever.

More broadly, the FDA’s latest guidance is a clear signal that the agency is committed to facilitating biosimilar access and competition. Sponsors that adapt quickly to this new environment — by embracing global harmonization, analytical rigor and strategic IP management — will be best positioned to capitalize on the unprecedented opportunities presented by the coming wave of biologic patent expirations.