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U.S. Biosimilar Landscape

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About this report

Biosimilars are a promising product category, one that can provide patients and doctors with more affordable treatment options.

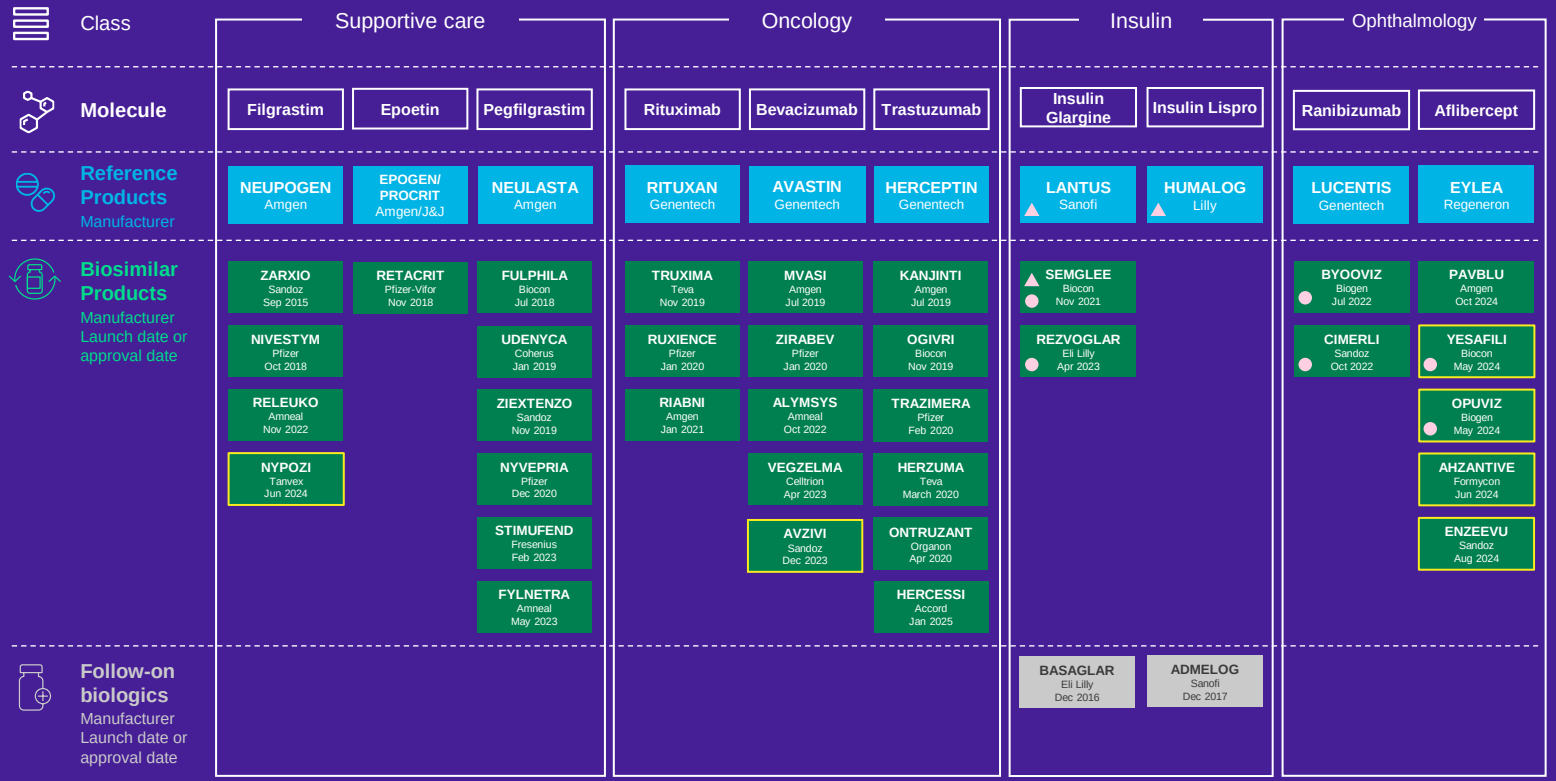
To date, there have been 63 approvals and 44 launches in the U.S. biosimilar market. As this market matures, its pipeline continues to grow. This reference guide is a useful tool to visualize and understand the current product landscape and potential future of this emerging market.

The market landscape chart is grouped by therapeutic class with Biosimilars and Follow-on Biologics organized in columns under the relevant molecule and Reference Product. Additional information regarding interchangeability designation ● and unbranded versions ▲ is highlighted via symbols.

The market pipeline charts show products that have not received FDA approval and are expected to launch in 1 to 4 years. These charts suggest a bright future for biosimilars, as they document a large number of existing and new suppliers investing in biosimilars.

U.S. biosimilar market landscape

As of January 1, 2025



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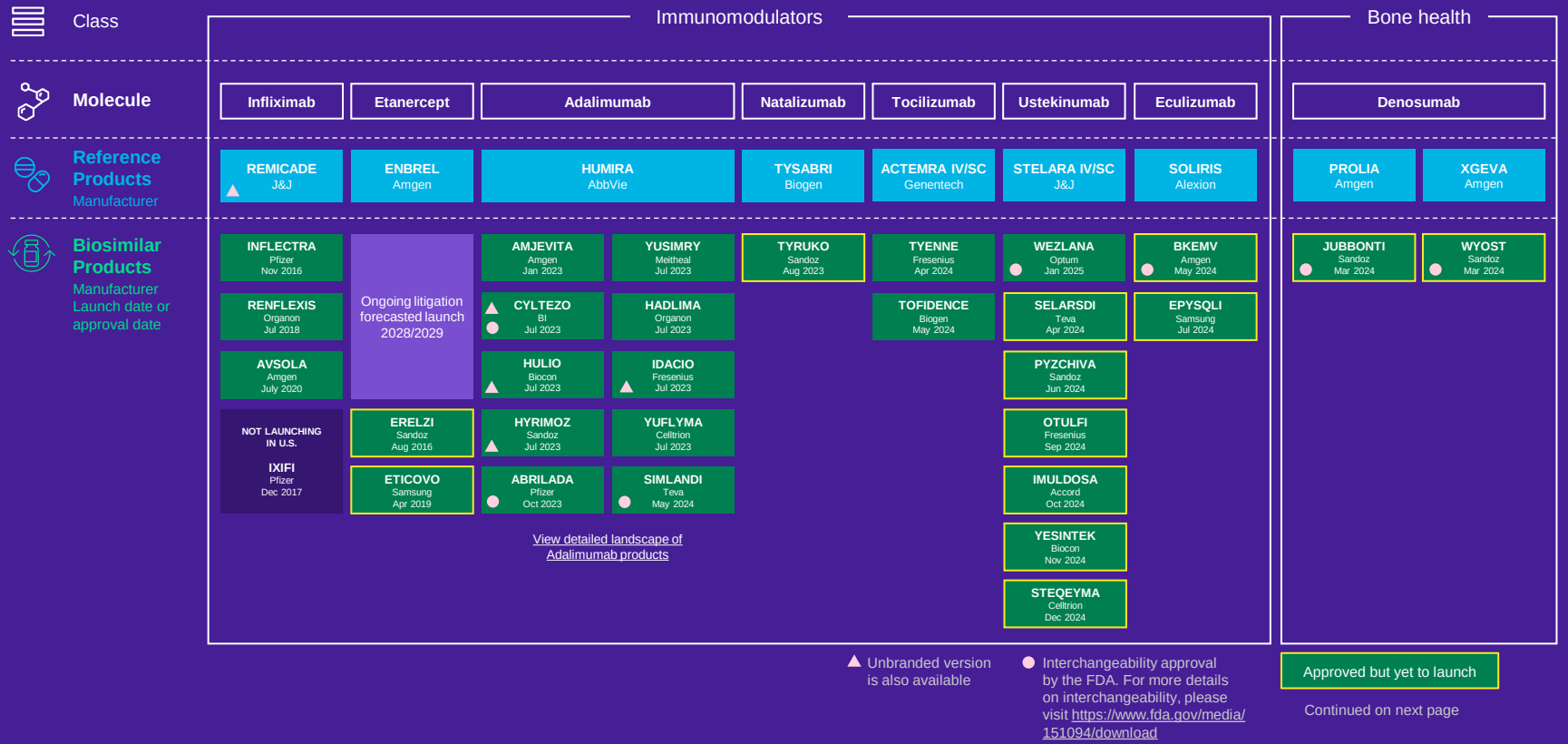
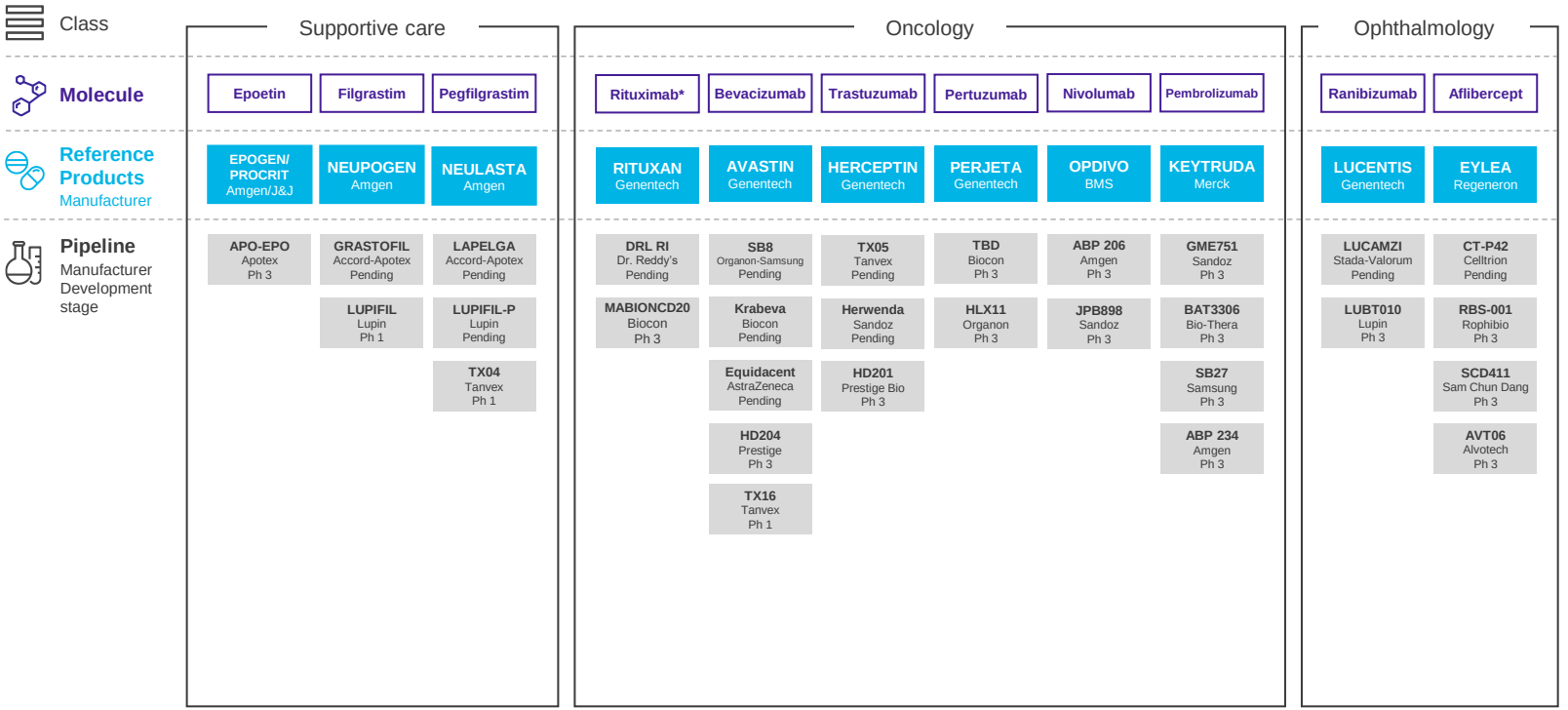
U.S. biosimilar market landscape

As of January 1, 2025



U.S. biosimilar pipeline landscape

As of January 1, 2025



Note: Pending is defined as any stage of development between BLA/aBLA submission and full FDA approval.
*Rituximab products are also approved for indications outside of oncology such as autoimmune indications.

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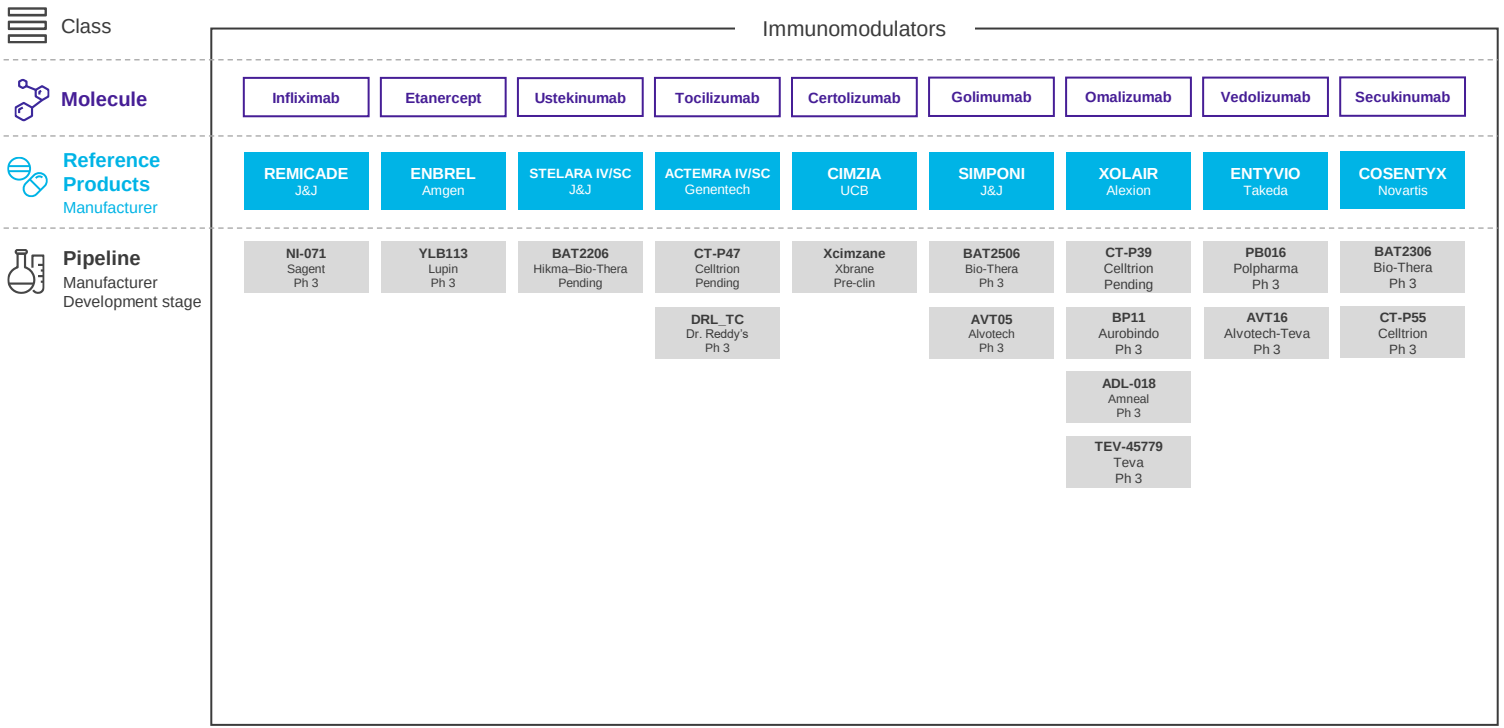
U.S. biosimilar pipeline landscape

As of January 1, 2025



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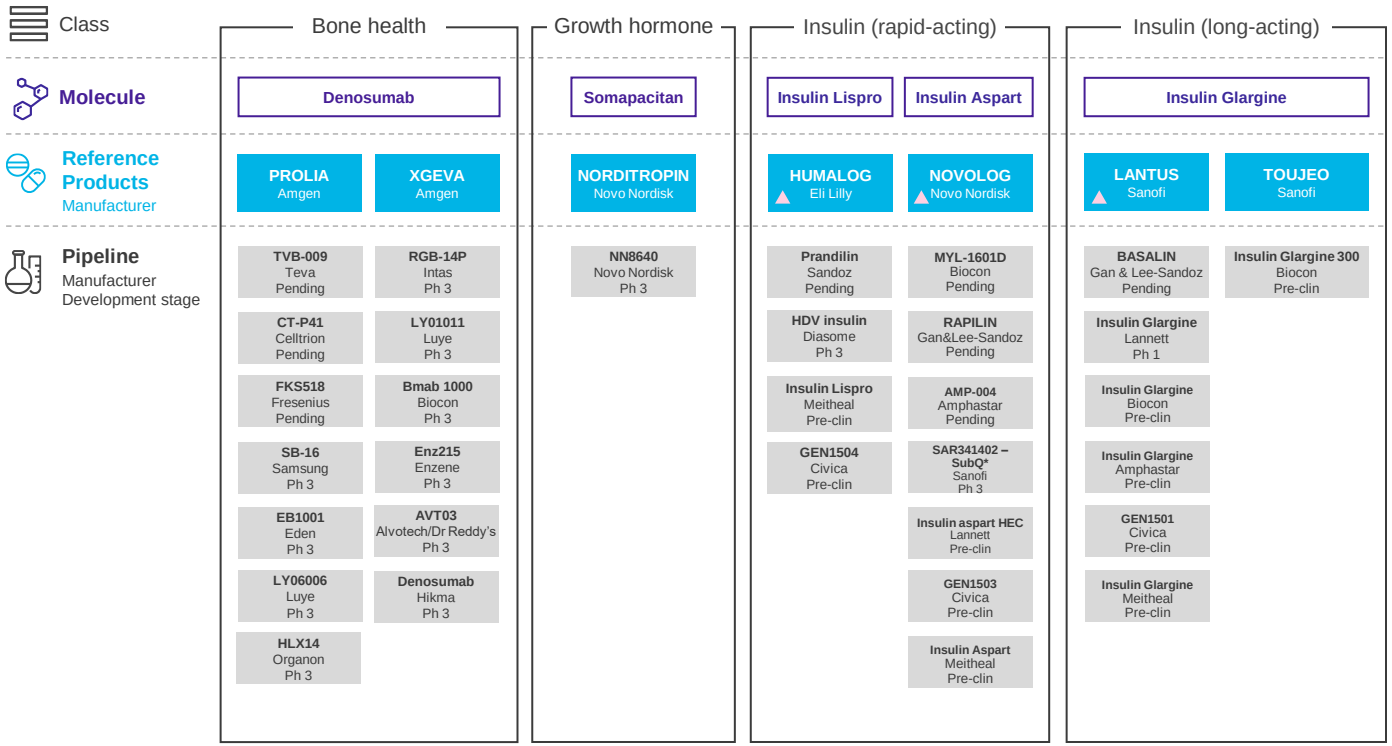
U.S. biosimilar pipeline landscape

As of January 1, 2025



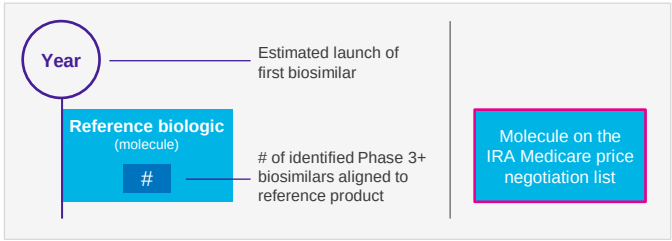
Note: Pending is defined as any stage of development between BLA/aBLA submission and full FDA approval.
*Indicates that a biosimilar product has a different route of administration than its innovator product.

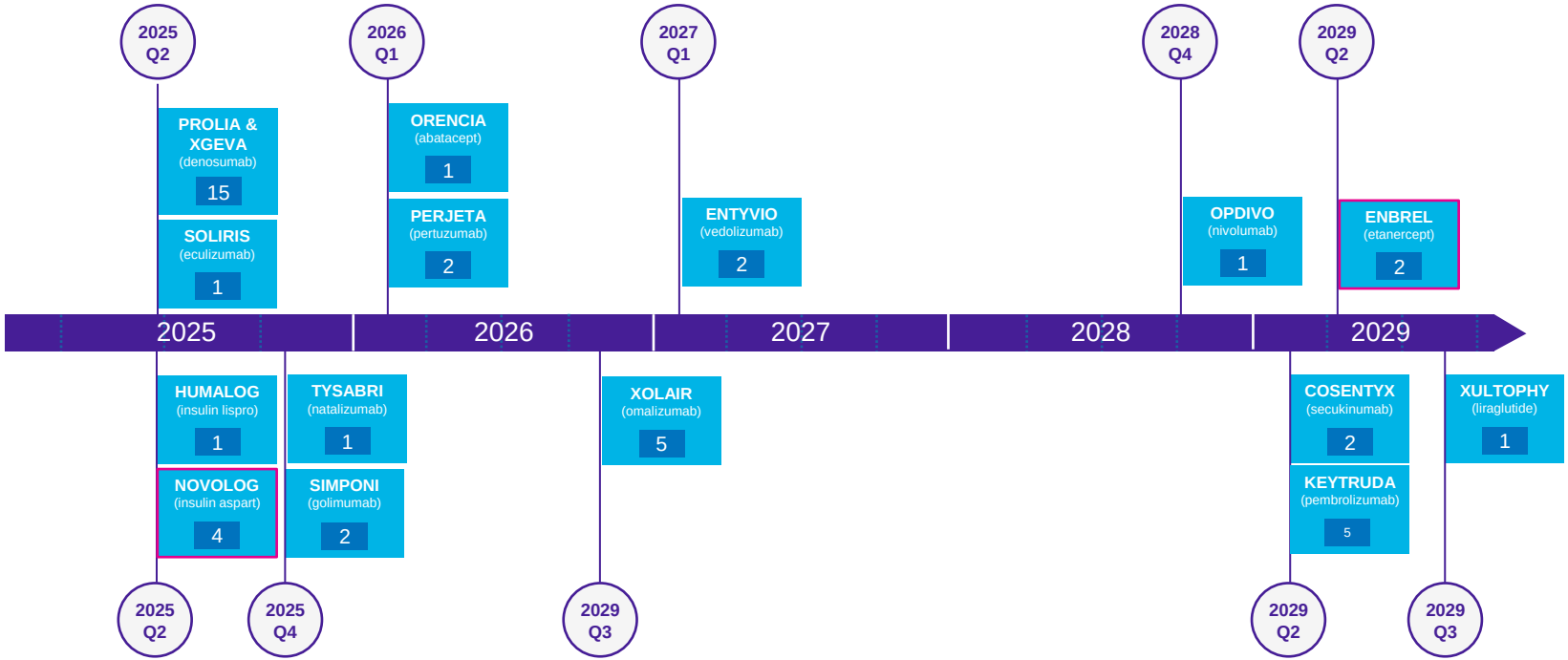
▲ Unbranded version is also available

● Interchangeability approval by the FDA. For more details on interchangeability, please visit https://www.fda.gov/media/151094/download

New biosimilar launches

Reference products included have no marketed biosimilars





Definitions

Product	Definition
Reference products[1]	A reference product is a single biological product, already licensed (approved) by the FDA under section 351(a) of the Public Health Service Act, against which a proposed biosimilar or interchangeable product is compared. A reference product is approved based on, among other things, a full complement of safety and effectiveness data.
Biosimilars[1]	A biosimilar product is a biological product that is highly similar to and has no clinically meaningful differences in terms of safety or effectiveness from an existing FDA-licensed (approved) reference product.
Interchangeable biosimilars[1]	An interchangeable product is a biological product that meets the requirements for a biosimilar product and is approved based on information that is sufficient to show that it can be expected to produce the same clinical result as the reference product in any given patient; and for a biological product that is administered more than once to an individual, there is not a greater safety risk or risk of reduced efficacy from alternating or switching between use of the interchangeable product and its reference product. An interchangeable product can be substituted for the reference product without the intervention of the prescribing healthcare provider.
Unbranded reference products[1]	An unbranded reference product generally describes an approved brand name biological product that is marketed under its approved BLA without its brand name (proprietary name) on its label. An “unbranded reference product” is not an “interchangeable biosimilar.” However, an unbranded reference product is considered by the FDA to be equivalent to its brand name biological product because it is the same product as the brand name biological product under the same BLA.
Follow-on biologics	A follow-on biologic is a competing brand product to a reference product and was approved under an NDA pathway before the biosimilar approval pathway (351k) was available.

Key: BLA – Biologics License Application; FDA – Food and Drug Administration; NDA – New Drug Application.

1. FDA. Purple Book. Last updated October 24, 2023. Accessed November 3, 2023. https://purplebooksearch.fda.gov/

Find out how Cencora is creating sustainability and longevity for biosimilars.

For more information, please contact us here.

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