

FDA's New Guidance on Biosimilar Labeling: A Step Towards Clarity and Confidence

TRENDING TOPICS

In the realm of healthcare, where innovation is the key to progress, the U.S. Food and Drug Administration (FDA) has been pivotal in advancing the accessibility of treatments through biosimilars. With over 40 biosimilar products (see figure 1) approved in the past eight years, biosimilars have proven to be essential alternatives to biologic medications, offering the same safety, purity, and effectiveness as their reference products.

The Importance of Biosimilars and Interchangeable Biosimilars

Biosimilars are not just crucial for healthcare providers and patients due to their therapeutic equivalence to the original biologics; they also represent a significant stride in patient care and cost reduction. An interchangeable biosimilar goes a step further, allowing pharmacy-level substitution without the need for prescriber approval, thereby simplifying treatment protocols and enhancing patient access to necessary medications.

Both biosimilars and interchangeable biosimilars are held to the same stringent standards of biosimilarity by the FDA. This assurance is critical as it underscores that patients and healthcare professionals can trust in the efficacy and safety of biosimilars, just as they would with the original biologic reference products.



Streamlining Communication: A Unified Biosimilarity Statement

The FDA has now recommended a refined approach to how biosimilars are labeled, favoring a single “Biosimilarity Statement” over separate statements for biosimilarity and interchangeability. This change reflects the accumulated experience of the FDA and aims to eliminate confusion among healthcare providers. It ensures that the focus remains on the critical scientific information necessary for the safe and effective use of the biosimilar products.

The rationale behind this move is multifaceted:

- It addresses scenarios where a single biosimilar application may cover both biosimilar and interchangeable products.
- It dispels any misconception that interchangeability implies a higher degree of safety or effectiveness.
- It centralizes information about interchangeability to the FDA’s Purple Book, making it more user-friendly for pharmacists who need this data for substitutions.

Impact on Prescribers and Pharmacists

For prescribers, this updated guidance means a streamlined process when prescribing biosimilars. The absence of an interchangeability statement in the labeling does not affect the product’s status or its ability to be interchanged; it merely clarifies the presentation of information.

Pharmacists, on the other hand, can refer to the Purple Book for comprehensive information on interchangeability to guide their substitution decisions. This separation of resources aligns with the different roles that prescribers and pharmacists play in patient care.

FDA Biosimilar Approvals by Year

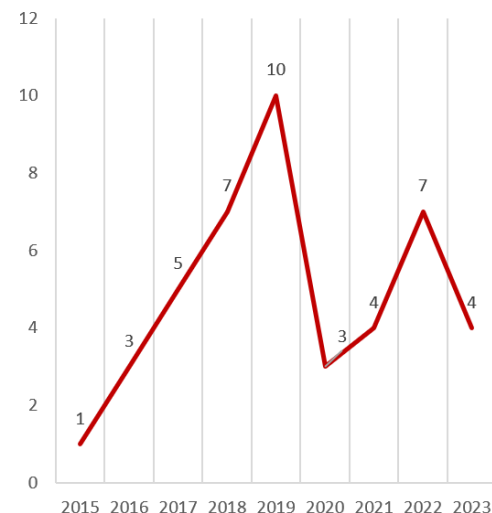


Figure 1 Correct as of 08/11/23



Side-by-side comparison of a biologic drug and its biosimilar

Biosimilar	Definition	Interchangeable Biosimilar
Highly similar to a reference biologic		Biosimilar that meets additional standards for interchangeability
Must demonstrate no clinically meaningful differences	FDA Approval Standard	Must demonstrate the same clinical result as the reference in any patient
Cannot be substituted without prescriber's consent	Substitution at Pharmacy	May be substituted without prescriber's consent (depending on state law)
Matches the reference product	Efficacy and Safety	Matches the reference product with the ability to switch back and forth
Biosimilarity statement only; previously had separate statements	Labelling Requirements	Biosimilarity statement only; no separate interchangeability statement
Prescribers must specify use of a biosimilar	Pharmacy & Prescriber Impact	Pharmacies can substitute interchangeable without contacting the prescriber

Old versus New labeling recommendations

Aspect	Old Labeling Recommendation	New Labeling Recommendation
Biosimilarity Statement	Separate biosimilarity and interchangeability statements	Unified biosimilarity statement for all biosimilars
Placement	In the Highlights section of labeling	In the Highlights section of labeling
Interchangeability	Specific interchangeability statement included if applicable	No separate interchangeability statement; information found in the Purple Book
Purpose	To inform of biosimilarity and potential interchangeability	To clearly state biosimilarity to the reference product
Example	"NEXSYMEO (replicamab-cznm) is biosimilar to JUNEXANT (replicamab-hjxf)" for biosimilars and "NEXSYMEO (replicamab-cznm) is interchangeable with JUNEXANT (replicamab-hjxf)" for interchangeable biosimilars	"NEXSYMEO (replicamab-cznm) is biosimilar to JUNEXANT (replicamab-hjxf)"
Rationale	Belief that interchangeability needed to be highlighted separately	Avoid confusion and reinforce that all biosimilars meet high standards of safety and efficacy

Table Footer Notes:

The new guidance aims to simplify the information and avoid implications that interchangeable biosimilars are superior to non-interchangeable biosimilars.

All biosimilars, whether interchangeable or not, have been rigorously evaluated for safety and efficacy.

The Purple Book is the authoritative source for information on the interchangeability of biosimilar products.

