BIOLOGICS HQ

VENABLE LLP



September 10, 2026

Latest News

Fresenius Kabi and Dr. Reddy's Announce Rituxan® Biosimilar Zimrixby™ (rituximab-cdxx) FDA Approval

Biocon Announces Launch of EYLEA® Interchangeable Biosimilar Yesafili™ While PGR Denied Institution

The FDA Finalizes Guidance on Formal Meetings for Drug and Biologic Development

Takeda Files First BPCIA Litigation Against Proposed Entyvio® (vedolizumab) Biosimilar, Polpharma's PB016

Second Proposed Interchangeable Vedolizumab aBLA from Alvotech and Teva Accepted by FDA

Read More News

Spotlight On

BiologicsHQ's "Spotlight On" dashboards provide, at a glance, an overview of the status of U.S. patent proceedings and FDA-approvals for biologic drugs and related biosimilars, and an overview of the status of U.S. biosimilar patent litigations through August 31, 2026.

Actemra® (tocilizumab)

Enbrel® (etanercept)

Herceptin® (trastuzumab)

Humira® (adalimumab)

Lantus® / Lantus® SoloSTAR®

Neulasta® (pegfilgrastim)

(insulin glargine)

Prolia® / Xgeva® (denosumab)

Rituxan® (rituximab)

Biosimilar Litigation Dashboard

IPRs and PGRs

- Eylea® (aflibercept): On August 6, 2026, the PTAB Director denied Biocon's PGR2026-00039 against Regeneron's U.S. Patent No. 12,168,036 for discretionary reasons as part of a bulk opinion with a note that a written opinion will be forthcoming. Biocon had filed a motion for joinder with PGR2025-00085.

Litigations

- Keytruda Qlex™ (pembrolizumab; berahyaluronidase alfa-pmph): On August 6, 2026, the Court in Case No. 2:25-cv-03179 (D.N.J.) stayed the litigation between Halozyme and Merck pending disposition of numerous related PGRs.
- Entyvio® (vedolizumab): On August 26, 2026, Takeda Pharmaceuticals filed BPCIA Litigation No. 3:26-cv-11002 (D.N.J.) against Polpharma alledging infringement of six patents by proposed Entyvio® (vedolizumab) biosimilar PB016.

aBLA Applications and FDA Activity

- Zimrixby™ (rituximab-cdxx): On August 3, 2026, Fresenius Kabi and Dr. Reddy's announced the FDA approval of Zimrixby™ (rituximab-cdxx), a biosimilar of Genentech's Rituxan® (rituximab).
- Yesafili® (aflibercept-jbvf): On August 3, 2026, Biocon announced the launch of Yesafili® (aflibercept-jbvf), an interchangeable biosimilar of Regeneron's Eylea® (aflibercept).
- AVT80 (subcutaneous vedolizumab): On August 31, 2026, Alvotech and Teva announced the FDA acceptance of an aBLA for AVT80 (vedolizumab), a proposed interchangeable biosimilar of Takeda's Entyvio® (vedolizumab). AVT80 is a subcutaneous presentation of vedolizumab. Alvotech and Teva announced the FDA acceptance of their intravenous presentation of vedolizumab, AVT16, in June 2026.

CDER Purple Book Updates

- Tudriqev™ (vusolimogene oderparepvec-wtpg): On August 6, 2026, the FDA granted accelerated approval to Replimune's Tudriqev™ (vusolimogene oderparepvec-wtpg).
- Genglycos™ (pariglasgene brecaparvovec-opnr): On August 19, 2026, the FDA approved Ultragenyx Pharmaceutical's Genglycos™ (pariglasgene brecaparvovec-opnr).

Non-U.S. Biosimilars / Follow-On Biologics

- Pegfilgrastim BS Biocon (pegfilgrastim-jmdb): On August 25, 2026, Biocon and Sandoz announced the approval of Pegfilgrastim BS Biocon (pegfilgrastim-jmdb), a biosimilar of Amgen's Neulasta®

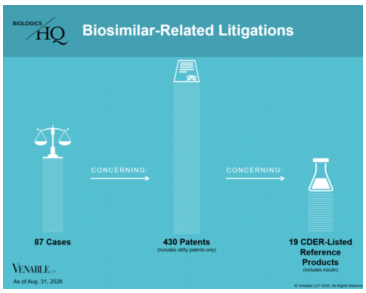
(pegfilgrastim), in Japan.

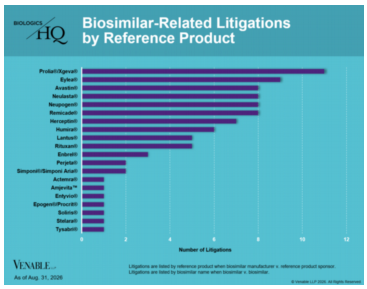
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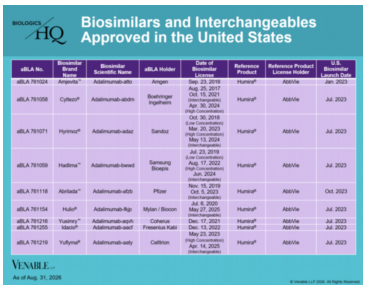
[Biosimilar-Related Litigations]

[Biosimilar-Related Litigations by Reference Product]

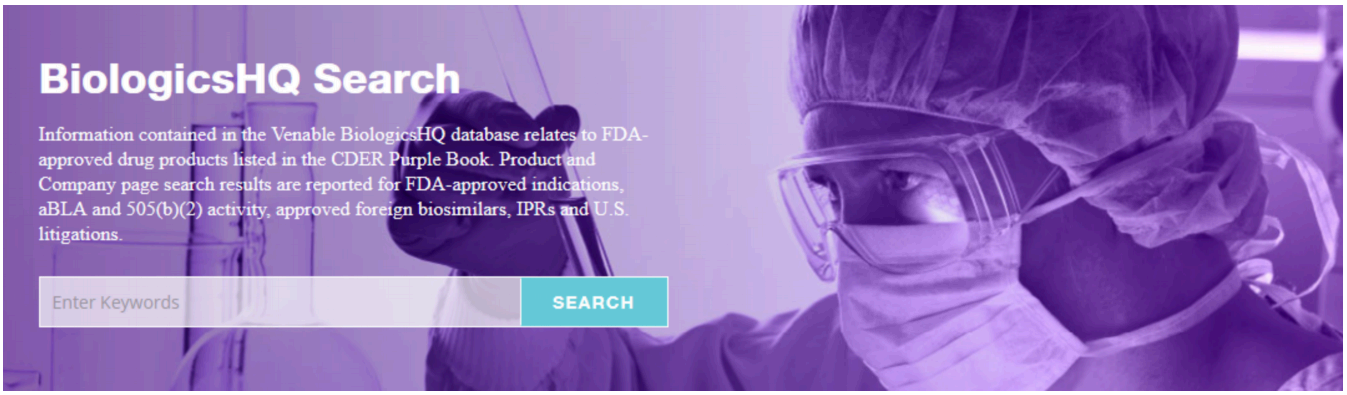
[Biosimilars and Interchangeables Approved in the United States]







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