

Approved and Pending Biosimilar Applications*

Biosimilar	Reference Product	Marketing Status	Litigation (Active or Pending)
<p><i>Name:</i> Zarxio (filgrastim-sndz)</p> <p><i>Manufacturer:</i> Sandoz</p> <p><i>BLA:</i> 125553</p>	<p><i>Name:</i> Neupogen® (filgrastim)</p> <p><i>Manufacturer:</i> Amgen</p> <p><i>BLA:</i> 103353</p> <p><i>Indications/Uses:</i> Treats neutropenia by increasing production of white blood cells. Often used for patients taking chemotherapy treatments or after bone marrow transplantation.</p>	<p><u>Approved by FDA on March 6, 2015.</u></p> <p>Commercial launch by Sandoz/Novartis in September 2015.</p>	Pending certiorari to the U.S. Supreme Court. Litigation in the U.S. District Court for the Northern District of California.
<p><i>Name:</i> Inflectra (infliximab-dyyb)</p> <p><i>Manufacturer:</i> Celltrion, Inc.</p> <p><i>BLA:</i> 125544</p>	<p><i>Name:</i> Remicade (infliximab)</p> <p><i>Manufacturer:</i> Janssen Biotech, Inc.</p> <p><i>BLA:</i> 103772</p> <p><i>Indications/Uses:</i> Inhibits tumor necrosis factor-alpha to reduce inflammation in patients with the following autoimmune diseases: rheumatoid arthritis, psoriatic arthritis, ulcerative colitis, Crohn's disease, and ankylosing spondylitis.</p>	<p><u>Approved by FDA on April 5, 2016.</u></p> <p>Pfizer/Celltrion reportedly preparing for October 3, 2016 commercial launch (180 days post-approval).</p>	Litigation in the U.S. District Court for the District of Massachusetts.

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<p><i>Name:</i> ABP 501</p> <p><i>Manufacturer:</i> Amgen</p> <p><i>BLA:</i> 761024</p>	<p><i>Name:</i> Humira® (adalimumab)</p> <p><i>Manufacturer:</i> AbbVie Inc.</p> <p><i>BLA:</i> 125057</p> <p><i>Indications/Uses:</i> Inhibits tumor necrosis factor-alpha to reduce inflammation in patients with the following autoimmune diseases: rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, Crohn's disease, ulcerative colitis, moderate to severe chronic psoriasis, moderate to severe hidradenitis suppurativa, and juvenile idiopathic arthritis.</p>	Pending FDA approval; received unanimous support (26-0) of approval by FDA's Arthritis Advisory Committee on July 12, 2016.	Litigation in the U.S. District Court for the District of Delaware.
<p><i>Name:</i> TBD</p> <p><i>Manufacturer:</i> Sandoz</p> <p><i>BLA:</i> 761042</p>	<p><i>Name:</i> Enbrel (etanercept)</p> <p><i>Manufacturer:</i> Amgen, Inc.</p> <p><i>BLA:</i> 103795</p> <p><i>Indications/Uses:</i> Inhibits tumor necrosis factor-alpha to reduce inflammation in patients with the following autoimmune diseases: rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis, and plaque psoriasis.</p>	Pending FDA approval; received unanimous support (20-0) of approval by FDA's Arthritis Advisory Committee on July 13, 2016.	Litigation the in the U.S. District Court for the District of New Jersey.

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<p><i>Name:</i> TBD</p> <p><i>Manufacturer:</i> Apotex</p> <p><i>BLA:</i> Unknown</p>	<p><i>Name:</i> Neulasta® (pegfilgrastim)</p> <p><i>Manufacturer:</i> Amgen</p> <p><i>BLA:</i> 125031</p> <p><i>Indications/Uses:</i> Treats neutropenia by increasing production of white blood cells. Often used for patients taking chemotherapy treatments or after bone marrow transplantation.</p> <p>Neulasta® is the long-acting formulation of Neupogen®.</p>	Pending FDA approval.	Litigation in the U.S. District Court for the Southern District of Florida and U.S. Court of Appeals for the Federal Circuit.
<p><i>Name:</i> Grastofil</p> <p><i>Manufacturer:</i> Apotex</p> <p><i>BLA:</i> Unknown</p>	<p><i>Name:</i> Neupogen® (filgrastim)</p> <p><i>Manufacturer:</i> Amgen</p> <p><i>BLA:</i> 103353</p> <p><i>Indications/Uses:</i> Treats neutropenia by increasing production of white blood cells. Often used for patients taking chemotherapy treatments.</p>	Pending FDA approval.	Litigation in the U.S. District Court for the Southern District of Florida.
<p><i>Name:</i> Retacrit</p> <p><i>Manufacturer:</i> Hospira</p> <p><i>BLA:</i> Unknown</p>	<p><i>Name:</i> EpoGen® or Procrit® (epoetin alfa)</p> <p><i>Manufacturer:</i> Amgen (EpoGen); Janssen Biotech (Procrit)</p> <p><i>BLA:</i> 103234</p>	Pending FDA approval; delayed after being issued a Complete Response Letter (“CRL”) by FDA in October	Litigation in the U.S. District Court for the District of Delaware.

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	<p><i>Indications/Uses:</i> Stimulates red blood cells to treat anemia. Often used for patients taking chemotherapy treatment or who have chronic renal failure.</p>	2015.	
<p><i>Name:</i> TBD (pegfilgrastim)</p> <p><i>Manufacturer:</i> Sandoz</p> <p><i>BLA:</i> Unknown</p>	<p><i>Name:</i> Neulasta® (pegfilgrastim)</p> <p><i>Manufacturer:</i> Amgen</p> <p><i>BLA:</i> 125031</p> <p><i>Indications/Uses:</i> Treats neutropenia by increasing production of white blood cells. Often used for patients taking chemotherapy treatments.</p> <p>Neulasta® is the long-acting formulation of Neupogen®.</p>	Pending FDA approval; delayed after being issued a CRL by FDA in Q2 2016.	Litigation in the U.S. District Court of New Jersey and the U.S. District Court for the Northern District of California.
<p><i>Name:</i> SB2</p> <p><i>Manufacturer:</i> Samsung/Merck</p> <p><i>BLA:</i> Unknown</p>	<p><i>Name:</i> Remicade (infliximab)</p> <p><i>Manufacturer:</i> Janssen Biotech, Inc.</p> <p><i>BLA:</i> 103772</p> <p><i>Indications/Uses:</i> Inhibits tumor necrosis factor-alpha to reduce inflammation in patients with the following autoimmune diseases: rheumatoid arthritis, psoriatic arthritis, ulcerative colitis,</p>	Pending FDA approval.	

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	Crohn's disease, and ankylosing spondylitis.		
<i>Name:</i> CHS-1701 <i>Manufacturer:</i> Coherus BioSciences <i>BLA:</i> Unknown	<i>Name:</i> Neulasta® (pegfilgrastim) <i>Manufacturer:</i> Amgen <i>BLA:</i> 125031 <i>Indications/Uses:</i> Treats neutropenia by increasing production of white blood cells. Often used for patients taking chemotherapy treatments. Neulasta® is the long-acting formulation of Neupogen®.	Pending FDA approval.	

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