

# Approval Process

## An overview of biosimilars in the oncology setting

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**BACKGROUND:** Following approval of the Biologics Price Competition and Innovation Act of 2009, biosimilars are gradually entering the market in the United States. With the introduction of more biosimilars into the marketplace, all healthcare providers should be familiar with the approval and evaluation process, the naming convention applied to these agents, and the importance of accurate pharmacovigilance.

**OBJECTIVES:** This article aims to describe the approval process of biosimilars, including extrapolation, and to help healthcare providers understand when a biosimilar may be interchanged for the reference biologic and the naming convention used for biosimilars. In addition, this article explores how these topics affect confidence in dispensing and pharmacovigilance.

**METHODS:** A literature review was conducted, and search terms and variation included *biosimilar agents AND FDA approval, legislation, interchangeability, naming conventions, confidence in dispensing, and pharmacovigilance.*

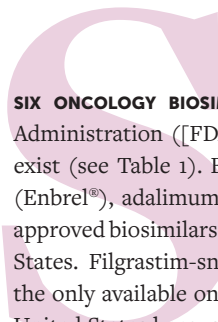
**FINDINGS:** Healthcare providers involved in the dispensing and administration of biosimilar and interchangeable biologics need to be continually educated to ensure confidence, familiarity, and accuracy with the processes surrounding biosimilars.

### KEYWORDS

biosimilar; legislation; interchangeability; pharmacovigilance

### DIGITAL OBJECT IDENTIFIER

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**SIX ONCOLOGY BIOSIMILARS ARE APPROVED** by the U.S. Food and Drug Administration ([FDA], 2018a), but a total of 12 FDA-approved biosimilars exist (see Table 1). Biologics with approved biosimilars include etanercept (Enbrel<sup>®</sup>), adalimumab (Humira<sup>®</sup>), and infliximab (Remicade<sup>®</sup>). Two FDA-approved biosimilars for infliximab are available for distribution in the United States. Filgrastim-sndz (Zarxio<sup>®</sup>) and pegfilgrastim-jmbd (Fulphila<sup>™</sup>) are the only available oncology biosimilars for purchase and distribution in the United States because the manufacturing and distribution of biosimilars for bevacizumab (Avastin<sup>®</sup>) and trastuzumab (Herceptin<sup>®</sup>) (i.e., bevacizumab-awwb [Mvasi<sup>™</sup>] and trastuzumab-dkst [Ogivri<sup>™</sup>], respectively) have been held up in litigation. This information can be referenced in the Purple Book, which is an online database that provides the names, dates of licensure, patent expiration dates, and other related information for biologics, including information on biosimilars (FDA, 2018c). The Purple Book also identifies if a biologic has been determined to be biosimilar to or interchangeable with the reference biologic.

### Biosimilars in Development

With several biologics nearing the end of their patent protection, several more biosimilars can be expected to be introduced into the market (FDA, 2018c; Panesar, 2016). Some of these include darbepoetin alfa (Aranesp<sup>®</sup>), cetuximab (Erbix<sup>®</sup>), rituximab (Rituxan<sup>®</sup>), and eculizumab (Soliris<sup>®</sup>) (FDA, 2018b).

### Legislation

The Biologics Price Competition and Innovation Act of 2009 (BPCIA) initially established the pathway for biosimilar approval in the United States and updated section 351(k) of the Public Health Service Act (FDA, 2016a). The BCPIA was enacted as part of the Patient Protection and Affordable Care Act of 2010 and created an abbreviated approval pathway for biologics that have demonstrated to be highly similar to or interchangeable with a currently marketed biologic. The BPCIA provided a 12-year exclusivity period from the date of first licensing of a reference biologic before the approval of any biosimilar can occur (Panesar, 2016). The FDA will not accept or consider an application for a biosimilar under this act until the fifth year after approval of the reference biologic.

If the FDA does not approve a biosimilar application, the agency will issue a complete response letter (Electronic Code of Federal Regulations, 2018). The contents of this letter include a description of the deficiencies that the agency has identified with the application, the FDA's complete review