

Welcome and Introductions



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Welcome



Sarah Yim, MD

Director, Office of Therapeutic Biologics and
Biosimilars (OTBB)
Office of New Drugs (OND)|CDER|FDA



Steven Kozlowski, MD

Chair, BsUFA III Regulatory Science
Subcommittee (RSSC)
Director, Office of Biotechnology Product
(OBP)|CDER|FDA



Susan Kirshner, MSc, PhD

Director, Division of Biotechnology
Review & Research III
Office of Biotechnology Product
(OBP)|CDER|FDA



Cate Lockhart, PharmD, PhD

Executive Director
Biologics and Biosimilar Collective Intelligence
Consortium (BBCIC)



Diane McCarthy, PhD

Senior Scientific Director, Global Biologics
U.S Pharmacopeia



Yow-Ming Wang, PhD

Associate Director for Biosimilars
Office of Clinical Pharmacology (OCP)
Office of Translational Sciences (OTS)
CDER|FDA



Kimberly Maxfield, PhD

Scientific Lead, BsUFA Regulatory Science
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Office of Therapeutic Biologics and
Biosimilars (OTBB)
Office of New Drugs (OND)|CDER|FDA

The State of Biosimilars at FDA

As of **October 5, 2023**:

- CDER has received meeting requests to discuss the development of biosimilars for **54** different reference products
- FDA has approved **43** 351(k) BLAs for biosimilar products, **6** of which are interchangeable; **38** are marketed

FDA Approved Biosimilar and Interchangeable Products*



Product Class		Approvals
Supportive Care	Filgrastim	B B B
	Epoetin	B
	Pegfilgrastim	B B B B B B
Oncology	Rituximab	B B B
	Bevacizumab	B B B B
	Trastuzumab	B B B B B
Autoimmune	Infliximab	B B B B
	Etanercept	B B
	Adalimumab	B I B B I B B B B
	Insulin Glargine	I I
	Natalizumab	B
	Tocilizumab	B
Ophthalmology	Ranibizumab	I I

Biosimilar
 Interchangeable Biosimilar

- 43 biosimilars approved to 13 different reference products
- 6 approved as interchangeable
- 38 marketed

*as of October 5, 2023

Biosimilars Are Delivering Savings and Expanding Patient Access



42
APPROVED
36
MARKETED

 **Biosimilar savings since 2015**
\$23.6 BILLION

 Biosimilars have been used in more than **694 MILLION DAYS** of patient therapy and have resulted in more than **344 MILLION INCREMENTAL DAYS** of therapy

 Biosimilar competition is driving lower prices among biosimilars and their reference products

Office of the Inspector General Report: [Biosimilars Have Lowered Costs for Medicare Part B and Enrollees, but Opportunities for Substantial Spending Reductions Still Exist \(hhs.gov\)](https://www.hhs.gov/office-of-the-inspector/reports/2018/01/biosimilars-have-lowered-costs-for-medicare-part-b-and-enrollees-but-opportunities-for-substantial-spending-reductions-still-exist)