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Welcome

- Sarah Yim, MD
 - Director, Office of Therapeutic Biologics and Biosimilars (OTBB) Office of New Drugs (OND) | CDER | FDA
- Chair BSLIFA III Regulatory

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
Pilot Program
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* FDA



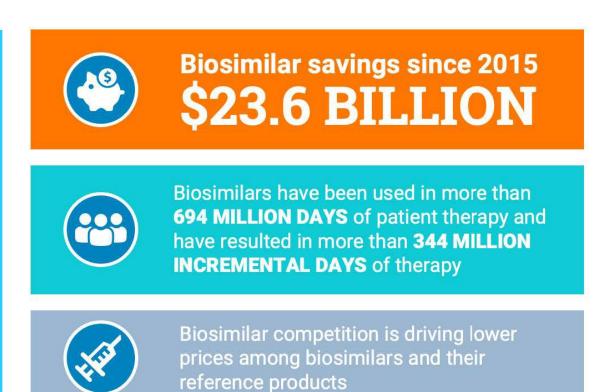
| Product Class | | Approvals | | | |
|-----------------|------------------|-----------|---|--------------------------------|----------------------------|
| | Filgrastim | BBB | | | B Biosimilar |
| Supportive Care | Epoetin | B | | | Interchangeable Biosimilar |
| | Pegfilgrastim | BBBBB | • | 43 biosimilar | s approved |
| Oncology | Rituximab | BBB | 1 | to 13 differen | |
| | Bevacizumab | BBBB | | products | |
| | Trastuzumab | BBBBB | • | 6 approved as | |
| Autoimmune | Infliximab | BBBB | | interchangeable 38 marketed | |
| | Etanercept | BB | • | | |
| | Adalimumab | BIBBBB | В | | |
| | Insulin Glargine | | | | |
| | Natalizumab | B | | | |
| | Tocilizumab | B | | | *as of October 5, 2023 |
| Ophthalmology | Ranibizumab | | | | 4 |

Biosimilars Are Delivering Savings and Expanding Patient Access



42 APPROVED 36

MARKETED



Office of the Inspector General Report: <u>Biosimilars Have Lowered Costs for Medicare Part B and Enrollees</u>, but Opportunities for Substantial Spending Reductions Still Exist (hhs.gov)