

GR_x + BIOSIMS EXPOSITION

Office of Therapeutic Biologics and Biosimilars

Center for Drug Evaluation and Research (CDER)
U.S. Food and Drug Administration (FDA)

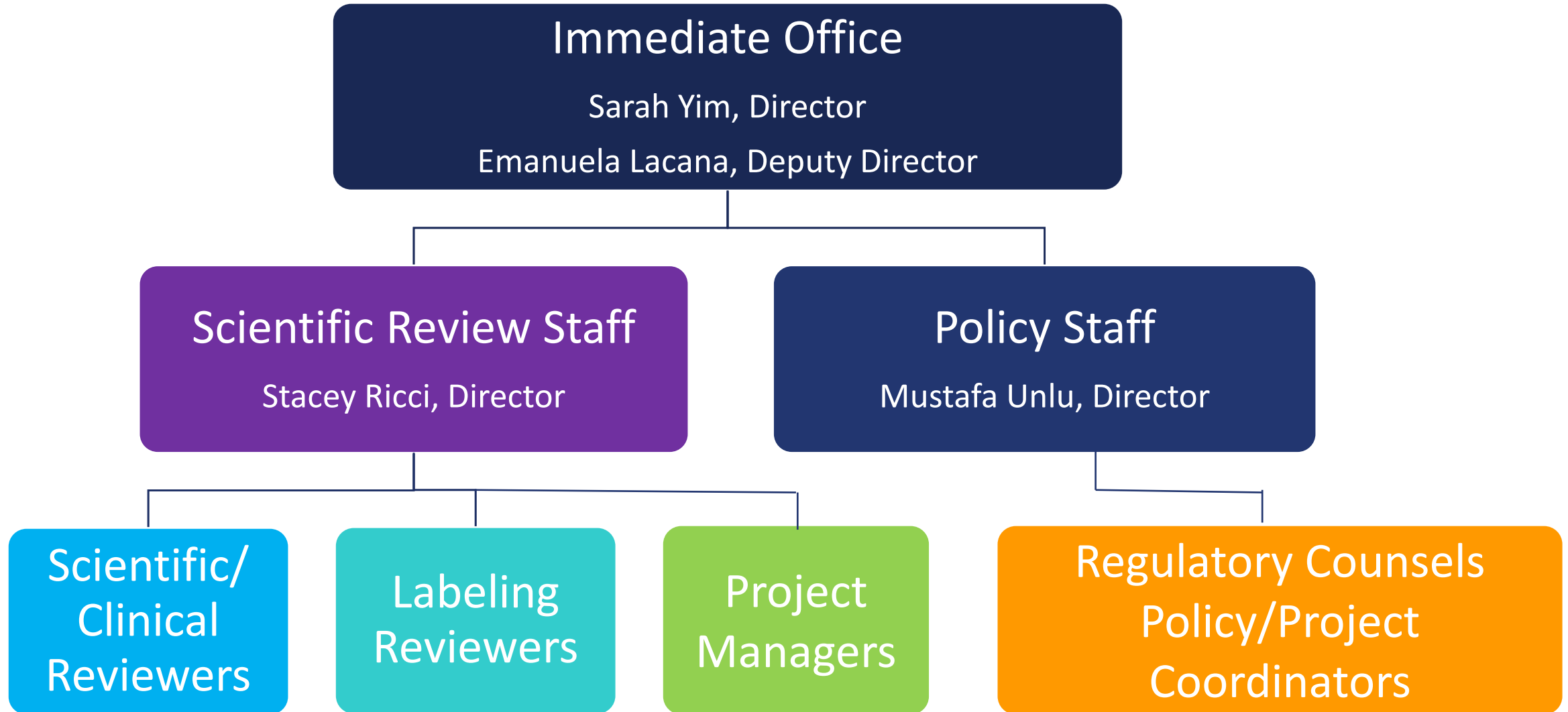
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OTBB Structure



Biosimilar Program Highlights



Approvals and Programs

61

Approved
Biosimilars to **17**
Reference products

16

Interchangeable
biosimilars

38

Currently Marketed
to **10** different
reference products

109

BS development
programs for
55 reference
products

As a result....



Biosimilar savings since 2015
\$36 BILLION



Biosimilars have been used in almost
2.7 BILLION DAYS of patient therapy and
have resulted in more than **495 MILLION
INCREMENTAL DAYS** of therapy



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

Source: AAM / 2024 U.S. Generic and Biosimilar Medicines Savings Report
<https://accessiblemeds.org/resources/blog/2024-savings-report>

FDA Approved Biosimilar and Interchangeable Biosimilars



61 Approved Biosimilars

17 Reference Products

41 Marketed

Filgrastim 4	Trastuzumab 6	Natalizumab 1	Aflibercept 5
Epoetin 1	Infliximab 4	Ranibizumab 2	Eculizumab 2
Pegfilgrastim 6	Etanercept 2	Tocilizumab 2	
Rituximab 3	Adalimumab 10	Ustekinumab 5	
Bevacizumab 5	Insulin Gargine 2	Denosumab 1	

Biological Product Regulation



- **351(a) “stand alone” BLA:** contains all information and data necessary to demonstrate that the proposed biological product is safe, pure and potent
- **The Biologics Price Competition and Innovation Act of 2009 (BPCI Act)**
 - Created an **abbreviated licensure pathway (351(k))** for biological products shown to be biosimilar to or interchangeable with an FDA-licensed reference product (originator biological product)

Key Definitions from the BPCI Act



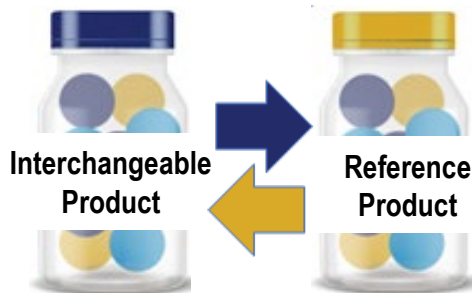
Reference Product

A reference product is the single biological product, already approved by FDA, against which a proposed biosimilar product is compared



Biosimilar Product

A biosimilar is a biological product that is **highly similar to and has no clinically meaningful differences from** an existing FDA-approved reference product



Interchangeable Product

- Is a biosimilar
- Expected to produce the same clinical result as the reference product (RP) in any given patient
- Switching between the proposed product and the RP does not ↑safety risks or ↓effectiveness compared to using the RP without switching

General Requirements



A 351(k) application must include information demonstrating that the biological product:

- Is **biosimilar** to a reference product
 - **Highly similar to and has no clinically meaningful differences from the FDA-approved reference product**
- Utilizes the **same mechanism(s) of action** for the proposed condition(s) of use -- but only to the extent the mechanism(s) are known for the reference product;
- **Condition(s) of use** proposed in labeling **have been previously approved** for the reference product;
- Has the **same route of administration, dosage form, and strength** as the reference product; and
- Is manufactured, processed, packed, or held in a facility that **meets standards** designed to assure that the biological product continues to be **safe, pure, and potent.**

Additional Resources

- www.fda.gov/biosimilars for access to all the education materials and information about biosimilar and interchangeable products.
- <https://purplebooksearch.fda.gov/> **The Purple Book: Database of Licensed Biological Products** for information on biological products, including if products are biosimilar to a reference product.
- www.fda.gov/drugsatfda (**Drugs@FDA**) for information on all FDA approved drug products, including labeling and review information.
- <https://www.fda.gov/drugs/biosimilars/curriculum-materials-health-care-degree-programs-biosimilars> for curriculum materials for health care degree programs
- [Guidance Webpage](#) for guidance related to BsUFA, including details on BPCI (search on “biosimilar”)
- [CDERLearn Training and Education](#) for FDA CE, Medscape CE, and other education content- select "biosimilars" under topics.



fda.gov/biosimilars

QUESTIONS?

ASK US ANYTHING!