Overview of BsUFA III

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SBIA BsUFA III Regulatory Science Pilot Program October 16, 2023

Basic User Fee Construct

- Congress directed FDA to establish a user fee program for the process for the review of biosimilar biological product applications. Fee funds are added to non-fee appropriated funds and are intended to increase staffing and other resources to speed and enhance review process.
- User fees pay for services that directly benefit fee payers.*
- Fee discussions with industry focus on desired enhancements in terms of specific aspects of activities related to review of biosimilar biological products.
  - What new or enhanced process will the FDA want or industry seek to include in the next 5 years?
  - What is technically feasible?
  - What resources are required to implement and sustain these enhancements?
  - **No discussion of policy** (e.g., FDA does not discuss what its policy decisions will be in guidance)
- Fee discussions also include mechanics of user-fee program (e.g., how fees are collected, fee types, products covered by each fee).
- Medical product user fee programs must be reauthorized every 5 years.

** OMB Circular A-25; direct benefit distinguishes user fees from tax*

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BsUFA I to BsUFA II

BsUFA I (FDASIA) | 2013-2017

- Referenced PDUFA fee amounts and included fees for products in the development phase in order to generate fee revenue to support FDA's review work during development and enable sponsors to have meetings with FDA early in development.
- Introduced predictable timelines and review process performance goals, primarily modeled on PDUFA, that increased over the course of BsUFA I.

BsUFA II (FDARA) | 2018-2022

- Established an independent, efficient user fee structure based on program costs.
- Implemented a review program ("the Program") to promote the efficiency and effectiveness of the first review cycle and minimize the number of review cycles necessary for biosimilar approval.
- Added commitments to assess the Program, clarify the regulatory pathway, and enhance staff capacity.

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BsUFA III Enhancement Areas

Supplements | Introducing new supplement types and expedited review timelines

Meeting Management | Enhancing communication and feedback during the biosimilar biological development process

Best Practices| Implementing best practices in communication during application review

URRA and Human Factors Timelines | Introducing timelines for review of URRA and Human Factors studies

Inspections| Enhancing pre-licensure inspection communication and clarifying use of alternative tools

Interchangeable Products| Introducing focused effort to advance the development of interchangeable products

Regulatory Science | Introducing new pilot program to enhance regulatory decision-making and facilitate science-based recommendations

Finance | Enhancing financial management and transparency

Hiring and Retention | Focusing on the strategic hiring and retention of world-class technical and scientific staff

Information Technology| Investing in modern technology to support enhanced and streamlined biosimilar product development and review

Supplements

- Relatively few BsUFA III category supplements submitted in FY23—draft guidance published 8/10/23

Category	Goal
Category A (original and resubmitted) Safety labeling updates	**3 months** of the receipt date FY2023: 70%, FY2024: 80%, FY2025-2027: 90%
Category B (original and resubmitted) Adding an indication w/o new data sets **Category C** (original and resubmitted) Removing an approved indication	**4 months** of the receipt date FY2023: 70%, FY2024: 80%, FY2025-2027: 90%
Category D (original and resubmitted) Adding an indication w/ new data sets (other than efficacy)	**6 months** of the receipt date FY2023: 70%, FY2024: 80%, FY2025-2027: 90%
Category E (original) Adding an indication w/ efficacy data sets **Category F** (original) Seeking initial determination of interchangeability	**10 months** of the receipt date FY2023-2027: 90%
Category E (resubmitted) **Category F** (resubmitted)	**6 months** of the receipt date FY2023-2027: 90%

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BsUFA Meeting Management

- **Modifies the BIA meeting so preliminary comparative analytical data is no longer required to meet with FDA.**

- **Introduces a new Biosimilar Product Development meeting type: Type 2a, focused on a narrow set of issues.**

- **Modifies timing of background packages for Type 4 meetings, so they may be submitted up to 14 days after FDA receipt of the written meeting request** (previously packages were submitted with the written request).

BsUFA Guidance Updates

Guidance for labeling of interchangeable products (9/30/2023)

- Draft biosimilar labeling guidance updated to include interchangeable products – **Released 9/18/23**

Guidance for formal meetings with industry (9/30/2023)

- Updated 2018 draft- **Released 8/10/23**

Guidance on classification of new supplement types (9/30/2023)

- **Released 8/10/23**

Best practices in communications (12/31/2023)

- Workshop on Best Practices in Communication held on 5/11/2022.
- Report received from Eastern Research Group (ERG) under working group review & recommendation

Guidance for device/presentations/CC for interchangeables (9/30/2025)

- In progress with working group

Medscape CE Courses

32,450
TOTAL LEARNERS

5,397
TOTAL MD LEARNERS

26,731
TOTAL OTHER HCP LEARNERS

13,315
TOTAL TEST TAKERS

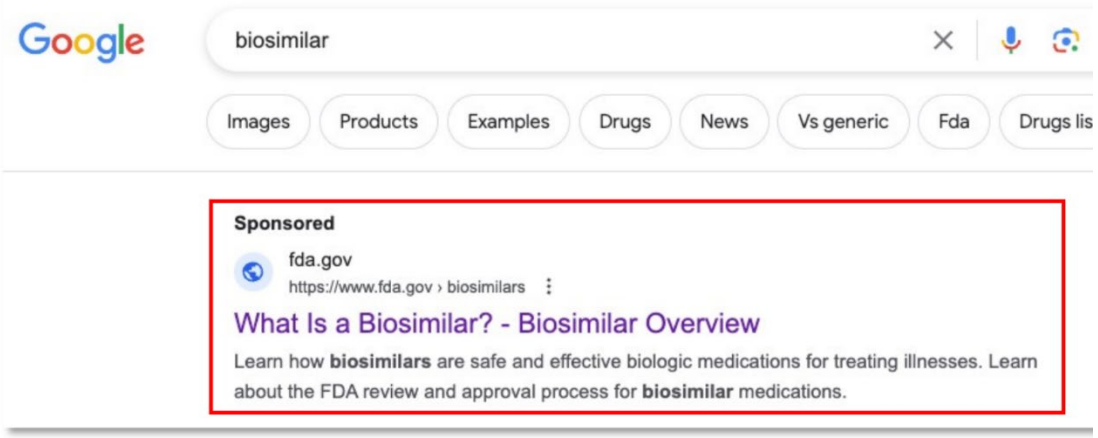
MD Learner Specialties

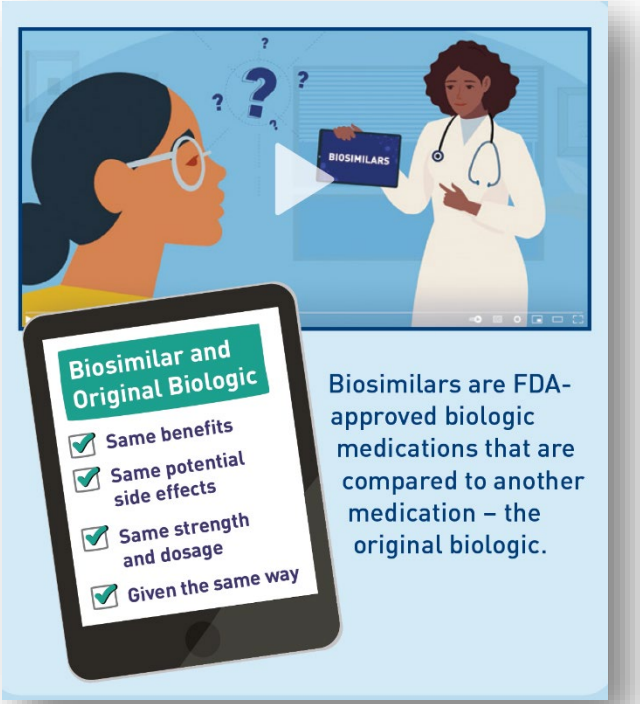
754	Rheumatologists
339	Gastroenterologists
140	Dermatologists
2,462	Primary Care Physicians
1,702	Other Physicians

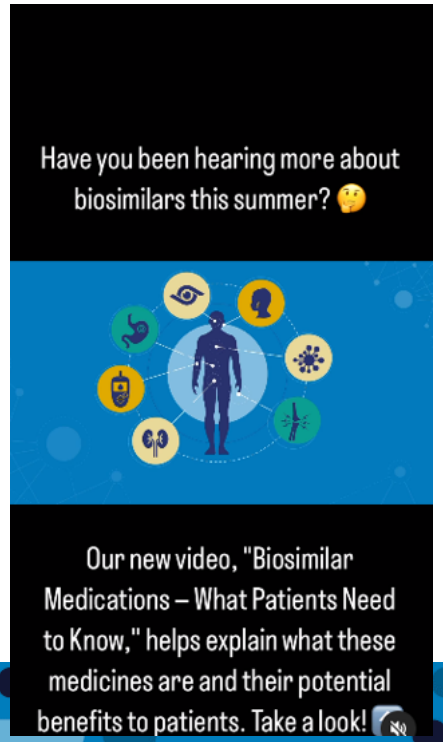
Other HCP Learners

2,494	Nurse Practitioners
219	Physician Assistants
15,672	Other Nurses
7,778	Pharmacists
568	Other HCPs

New Outreach and Education Activities







Thank you!