U.S. FOOD & DRUG ADMINISTRATION

WELCOME

We will begin the meeting promptly at 9:00am.

U.S. FOOD & DRUG ADMINISTRATION

Public Meeting on the Reauthorization of the Biosimilar User Fee Amendments (BsUFA)

Wednesday December 3, 2025

Welcome and Introduction

Jonathan Collins

Center for Drug Evaluation and Research, FDA

Meeting Moderator, Program Evaluation and Implementation Staff,
Office of Program and Strategic Analysis, Office of Strategic Programs

AGENDA

- Welcome and Introduction
- Opening Remarks
- BsUFA Background and Reauthorization Process
- Industry Comments
- **Break**
- Public Comment
- Closing Remarks

Submit your public comments by January 2nd!

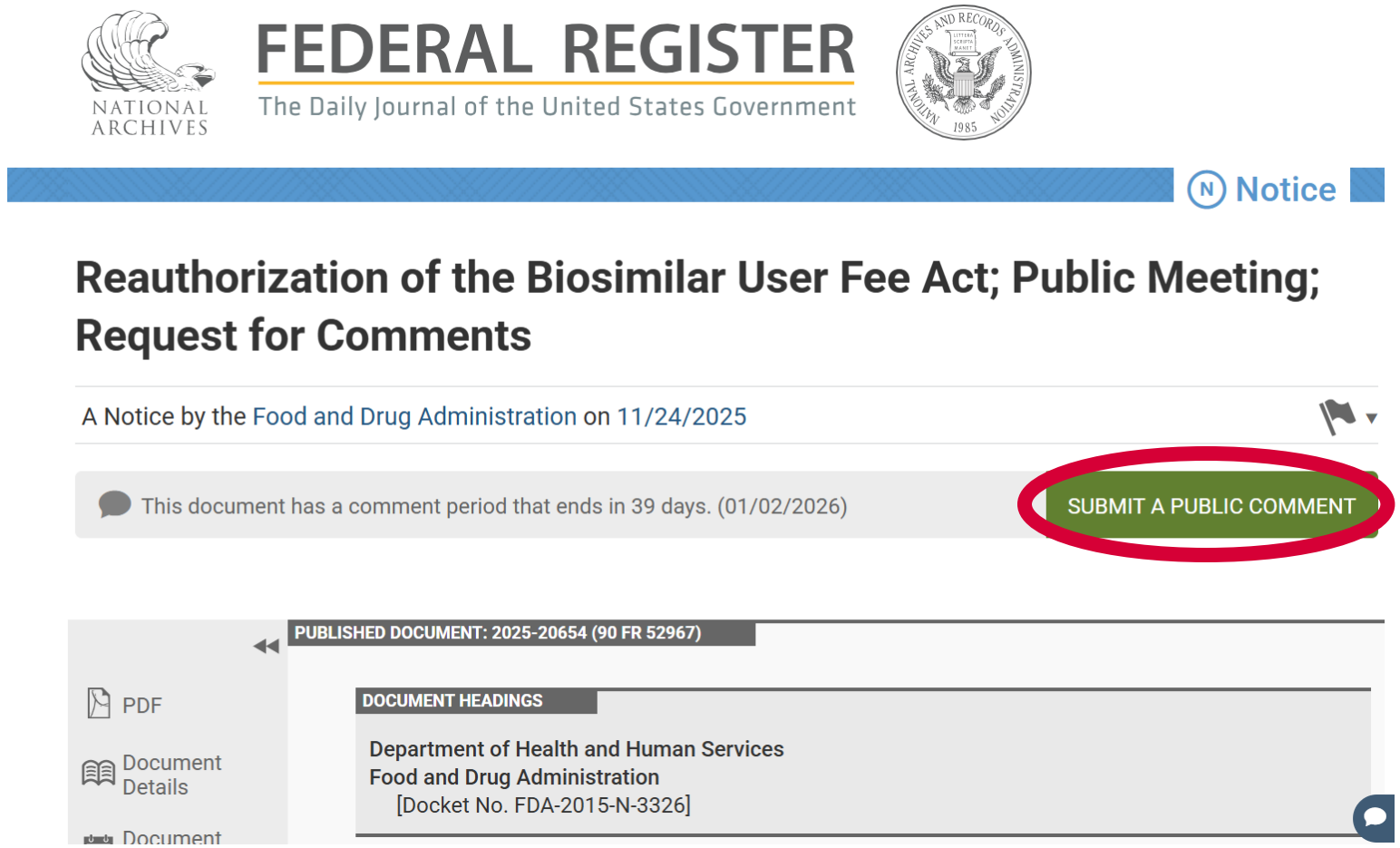
You can access the docket via:

- FDA's public meeting webpage

  (https://www.fda.gov/industry/public-meeting-reauthorization-biosimilar-user-fee-act-bsufa-12032025)

- Directly through the Federal Register

  (https://www.federalregister.gov/documents/2025/11/24/2025-20654/reauthorization-of-the-biosimilar-user-fee-act-public-meeting-request-for-comments)



Opening Remarks

Mike Davis

Center for Drug Evaluation and Research, FDA

Deputy Center Director

BsUFA Background and Reauthorization Process

Andrew Kish

Center for Drug Evaluation and Research, FDA

Director, Office of Program and Strategic Analysis, Office of Strategic Programs

Briefing Outline

- BsUFA Background
- Review Program and Performance
- Financial Background and Fee Structure
- Reauthorization Process Overview

BsUFA Background

BsUFA is now over 10 years old

- The Biologics Price Competition and Innovate Act of 2009 (BPCI Act) directed FDA to develop recommendations for a user fee program for 351(k) applications for FY 2013 – FY 2017.
- After consultation with regulated industry and public stakeholders, FDA transmitted recommendations to Congress on January 13th, 2012. The Food and Drug Administration Safety and Innovation Act (FDASIA) of 2012 included the first authorization of BsUFA.
- In 2011-2012, there were no marketing applications or products on the market, established drug development process or history related to biosimilar biological products.
- BsUFA is in its 13th year. Since its creation, BsUFA facilitated the approval of 79 biosimilar biological products for the American public.

BsUFA was established in 2012 to speed delivery of safe and effective biosimilar biological products

BsUFA I (2013 to 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 (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.

BsUFA was established in 2012 to speed delivery of safe and effective biosimilar biological products

BsUFA III (2023 - 2027):

- Introduced new supplement types and expedited review timelines
- Introduced timelines for review of Use-Related Risk analysis and Human Factors studies
- Introduced new pilot regulatory science program to enhance regulatory decision-making and facilitate science-based recommendations
- Introduced focused effort to advance the development of interchangeable products

Basic User Fee Construct

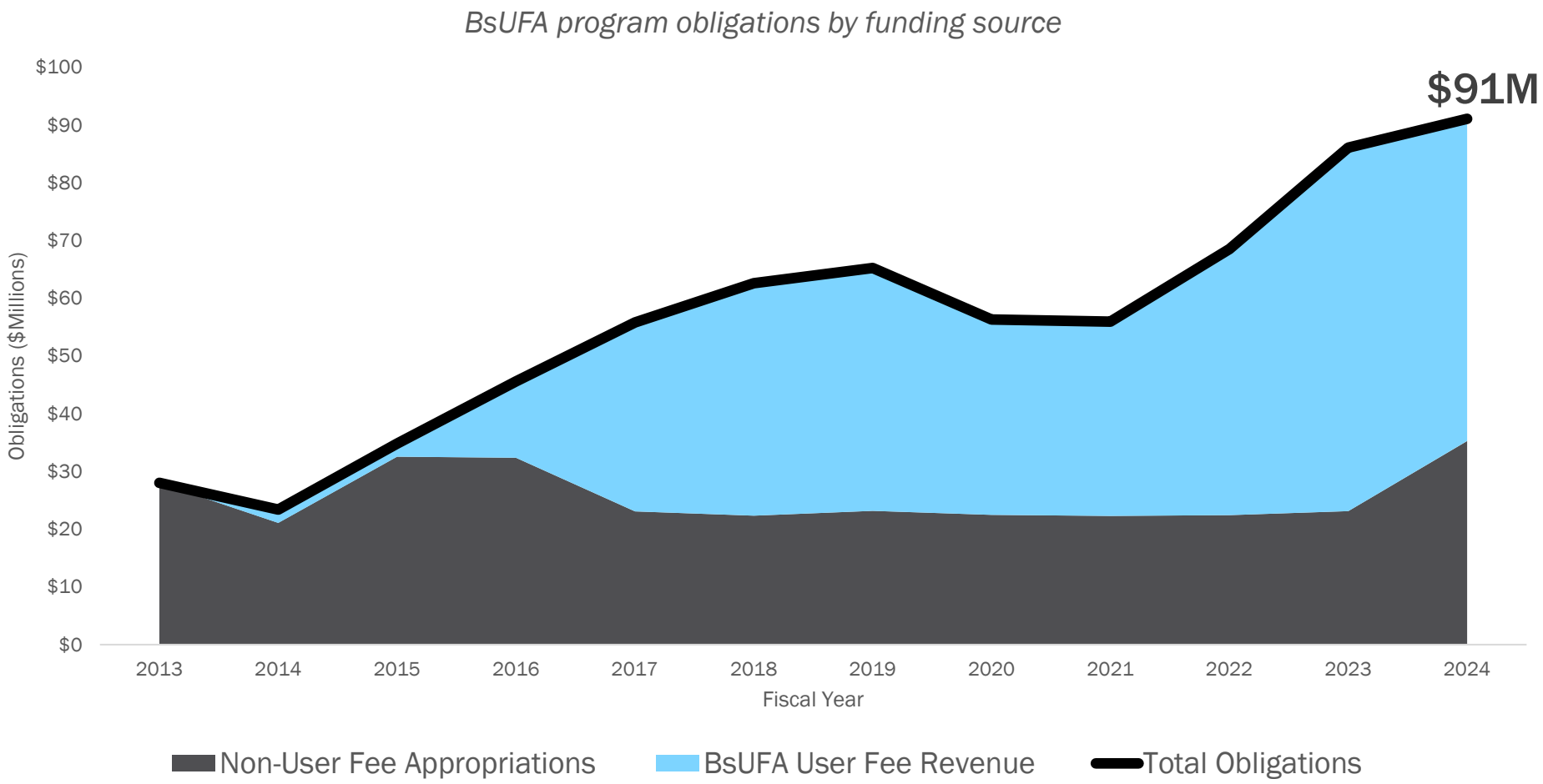
- Congress directed FDA to establish a user fee program for the process for the review of biosimilar biological product applications. Fee funds are added to non-fee appropriated funds and are intended to increase staffing and other resources to speed and enhance review process.
- User fees pay for services 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*

Financial Background and Fee Structure

User fee revenue is critical to the program.

BsUFA user fee revenue funded **61% of the program** in FY2024.



Current Fee Structure

FY 2026 target revenue is $55,841,000.

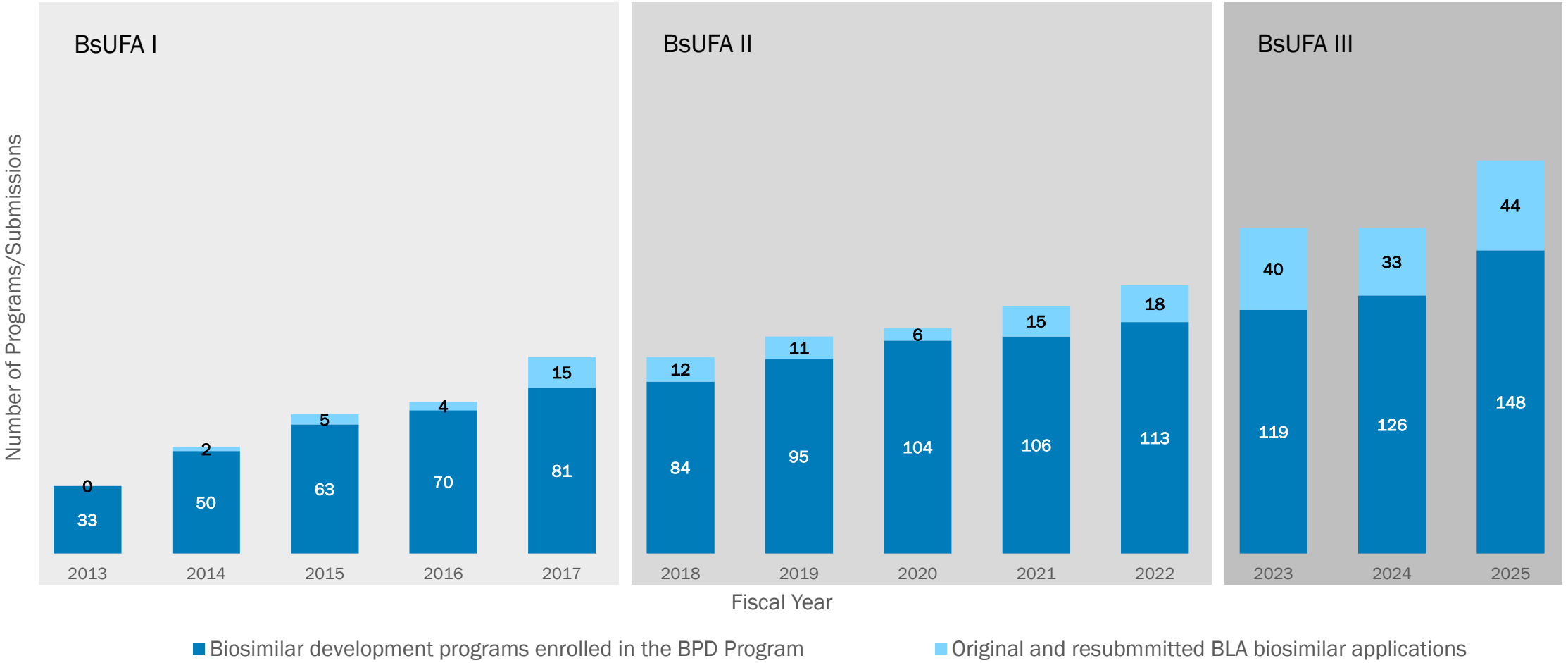
- 3% collected from initial, annual, and reactivation fees for the BPD Program ($1,500,000)
- 34% collected from applications ($19,212,704)
- 63% collected from program fees for the BPD Program ($35,128,296)

User Fee Type		FY2026
Biosimilar Biological Product Development (BPD) Fee	Initial BPD	$10,000
	Annual BPD	$10,000
	Reactivation	$20,000
Application Fee	Clinical Data Required	$1,200,794
	Clinical Data Not Required	$600,397
Program Fee		$209,907

Review Program and Performance

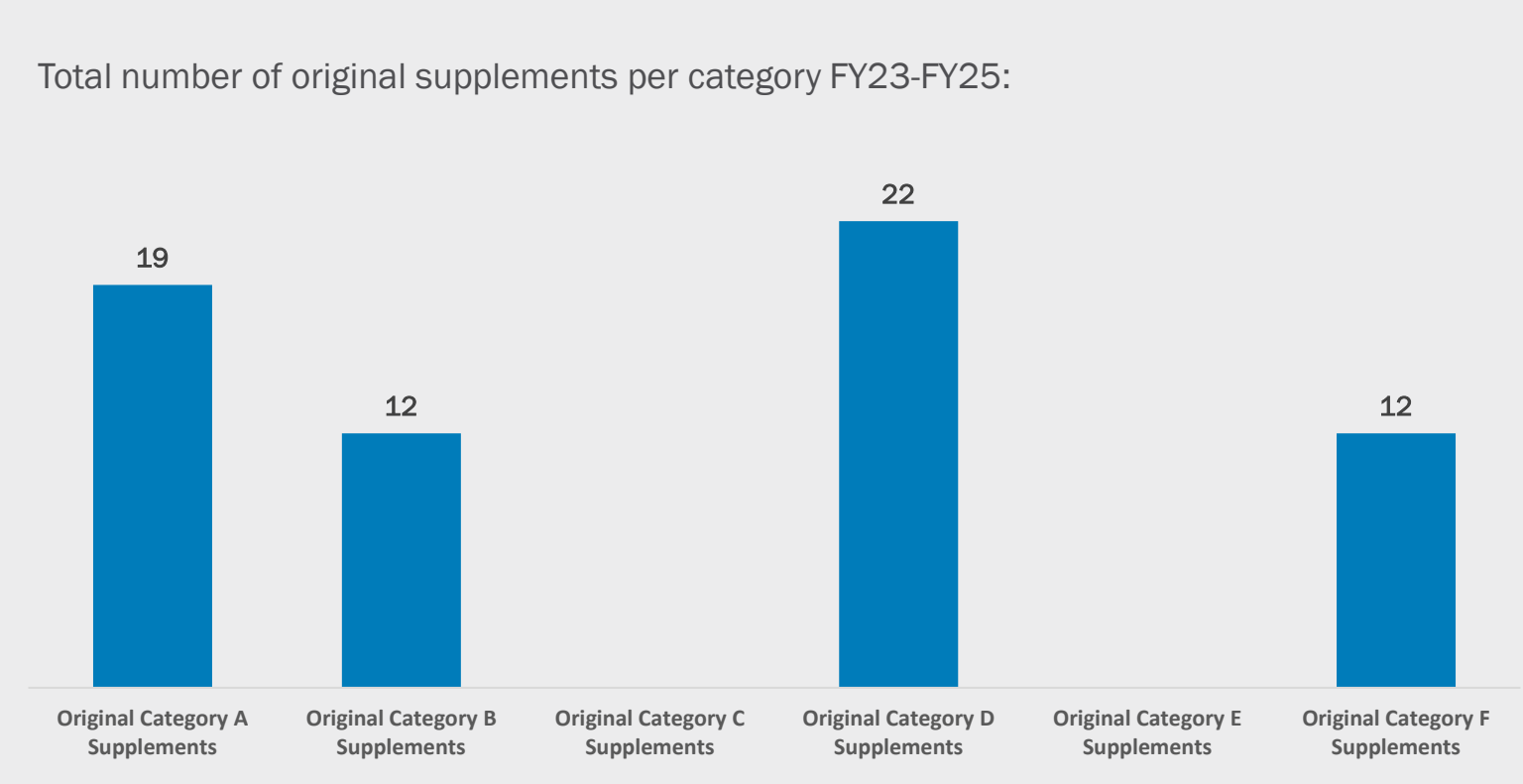
Biosimilar development is increasing.

Both BPD program enrollment and submitted biosimilar applications have increased from BsUFA I to BsUFA III.

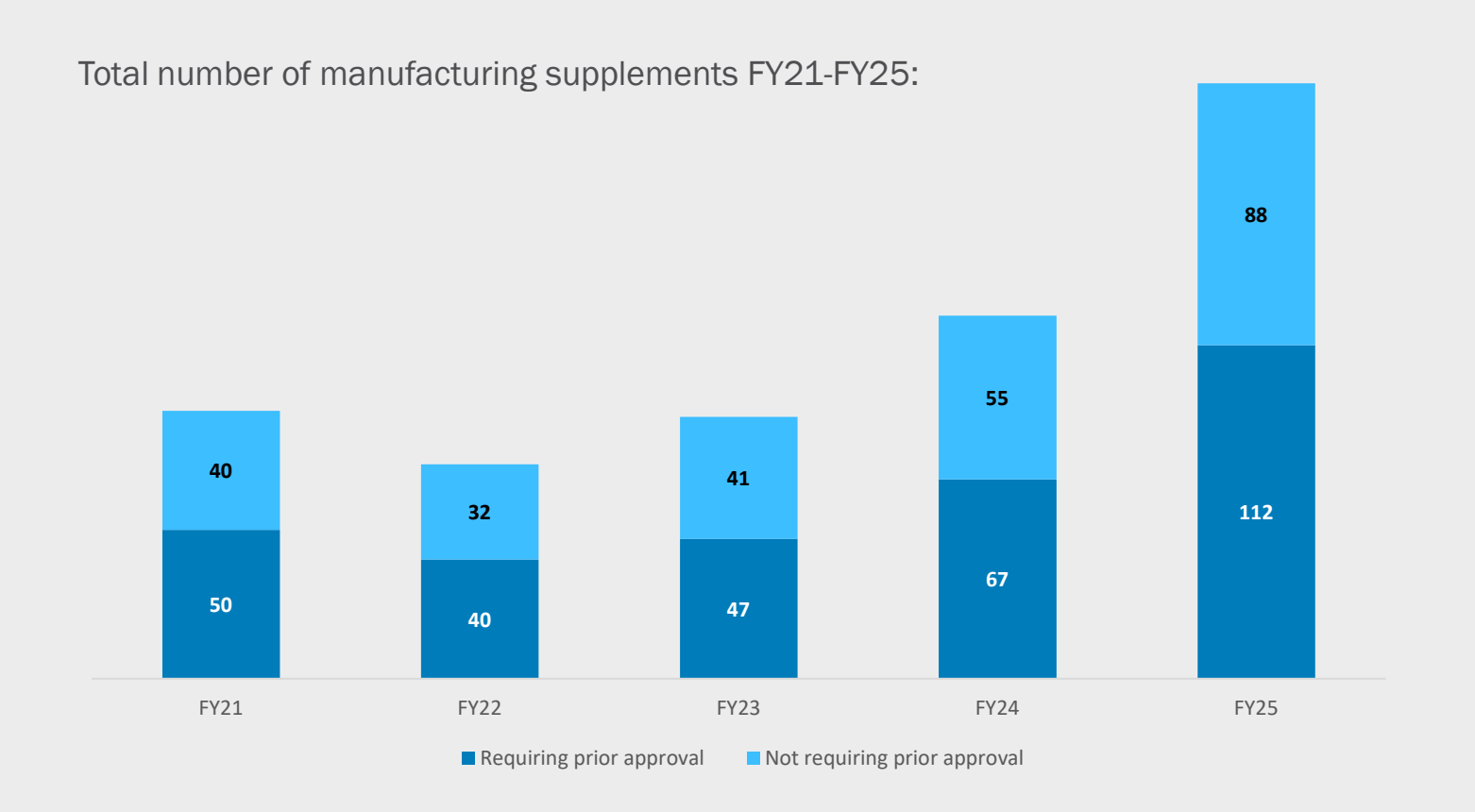


FDA has received 65 biosimilar efficacy supplement submissions under BsUFA III.

Majority of original supplement filings are in Category A and D, with Category C and E having zero filings.



Manufacturing supplement review workload continues to grow, with notable increases in the last two years.



Meeting management is also growing, with FDA handling over 100 BsUFA meeting requests annually.

	FY 2021	FY 2022	FY 2023	FY 2024	FY 2025
Biosimilar Initial Advisory Meeting Requests	6	9	14	18	28
BPD Type 1 Meeting Requests	4	14	8	10	13
BPD Type 2 Meeting Requests	90	97	--	--	--
BPD Type 2a Meeting Requests	--	--	36	45	53
BPD Type 2b Meeting Requests	--	--	52	74	76
BPD Type 3 Meeting Requests	7	2	1	0	3
BPD Type 4 Meeting Requests	10	13	24	16	13
Total meetings per fiscal year	**117**	**135**	**135**	**163**	**186**

Fees support review work against a broad set of performance commitments

BsUFA III includes 43 review, procedural, and meeting management goals; in addition to other commitments

EXAMPLE	GOAL
Original & Resubmitted Original Biosimilar Biological Product Applications	90% of standard applications within 10 months of filing 90% of resubmitted standard applications within 6 months of receipt
Original & Resubmitted Supplements with Clinical Data	90% of category A-D supplements within 60 days of receipt 90% of category E-F supplements within 74 days of receipt
Manufacturing Supplements	90% of prior approval supplements within 4 months of receipt 90% of non-prior approval supplements within 6 months of receipt
Major Dispute Resolution	90% of responses within 30 days of receipt
Clinical Hold Response	90% of clinical hold responses within 30 days of receipt
Special Protocol Assessments (SPA)	90% of SPAs and agreement requests within 45 days of receipt
Meeting Minutes	90% of minutes issued within 30 days of the meeting

Historically, FDA has met most review goals.

	Performance Against Goal By Fiscal Year						
Review Goal (90% on time)	*FY2018*	*FY2019*	*FY2020*	*FY2021*	*FY2022*	*FY2023*	*FY2024*
Original Biosimilar Product Applications	100%	86%	50%	90%	91%	92%	96%
Resubmitted Original Biosimilar Applications	100%	75%	100%	100%	100%	75%	100%
Original Supplements with Clinical Data	100%	100%	100%	90%	75%		
Original Category A Supplements						80%	100%
Original Category B Supplements						100%	100%
Original Category C Supplements						N/A	N/A
Original Category D Supplements						100%	80%
Original Category E Supplements						N/A	N/A
Original Category F Supplements						100%	100%
Manufacturing Supplements Requiring Prior Approval	100%	100%	95%	94%	93%	100%	93%
Manufacturing Supplements Not Requiring Prior Approval	100%	100%	97%	100%	97%	98%	98%

** This column is the current performance as of 9/30/25, and does not include performance goals for pending applications.*

Meeting management has improved

CDER and CBER meeting management performance by FY

** FY 25 numbers are preliminary*

	Performance by Fiscal Year				
Meeting Management Goal	*2021*	*2022*	*2023*	*2024*	*2025**
Biosimilar Initial Advisory Meeting Requests	83%	100%	93%	100%	96%
BPD Type 1 Meeting Requests	100%	86%	88%	100%	100%
BPD Type 2a Meeting Requests			86%	96%	90%
BPD Type 2b Meeting Requests	83%	89%	88%	99%	96%
BPD Type 3 Meeting Requests	86%	100%	100%		100%
BPD Type 4 Meeting Requests	80%	85%	92%	88%	100%
Biosimilar Initial Advisory Meetings Scheduled	100%	75%	91%	100%	86%
BPD Type 1 Meetings Scheduled	75%	71%	100%	78%	78%
BPD Type 2a Meeting Scheduled			79%	81%	96%
BPD Type 2b Meeting Scheduled	84%	90%	93%	90%	92%
BPD Type 3 Meeting Scheduled	83%	100%	100%		100%
BPD Type 4 Meeting Scheduled	70%	77%	71%	81%	92%
Biosimilar Initial Advisory Written Response	100%	100%	100%	90%	100%
BPD Type 2a Written Response			100%	93%	96%
BPD Type 2b Written Response	91%	93%	56%	100%	83%
Preliminary Response for BPD Type 2b Meetings	81%	88%	93%	95%	95%
Preliminary Response for BPD Type 3 Meetings	83%	100%	100%		100%
Meeting Minutes for All Meeting Types	85%	93%	87%	93%	96%

Note: *Type 2A meetings initiated in FY 23.*

We are on track to meet performance enhancement commitments.

In addition to the performance review goals under BsUFA III, FDA is implementing **nearly 100 actions to fulfill BsUFA III performance enhancement commitments**. These include:

- **30** data/list postings to the public website
- **22** new or updated pilots, programs or processes
- **16** new or revised guidances
- **11** Internal operating or strategy documents
- **8** public meetings or public workshops
- **4** public reports
- **2** hiring goals
- **2** third-party assessments

These performance enhancement commitments include…

- Establishing a BsUFA Regulatory Science Pilot Program
- Enhancing the Review Process and Sponsor Communication
- Clarifying the 351(k) Regulatory Pathway
- Enhancing Management of User Fee Resources
- Improving FDA Hiring and Retention of Review Staff

Performance data and completed deliverables are available to the public.

Completed BsUFA III deliverables can be found on FDA's website:

https://www.fda.gov/industry/biosimilar-user-fee-amendments/completed-bsufa-iii-deliverables

FDA released a BsUFA performance dashboard that allows users to view and download current and historical performance data:

https://www.fda.gov/about-fda/fda-track-agency-wide-program-performance/fda-track-biosimilar-user-fee-act-bsufa-performance-dashboards

Reauthorization Process Overview

Overview of BsUFA Reauthorization

BsUFA reauthorization involves significant consultation with stakeholders.

BsUFA REAUTHORIZATION and REPORTING REQUIREMENTS.

(f) REAUTHORIZATION.—

***(1) CONSULTATION.**—In developing recommendations to present to the Congress with respect to the goals, and plans for meeting the goals, for the process for the review of human drug applications for the first 5 fiscal years after fiscal year 2027, and for the reauthorization of this subpart for such fiscal years, the Secretary shall consult with— (A) the Committee on Energy and Commerce of the House of Representatives; (B) the Committee on Health, Education, Labor, and Pensions of the Senate; (C) scientific and academic experts; (D) health care professionals; (E) representatives of patient and consumer advocacy groups; and (F) the regulated industry.*

***(2) PRIOR PUBLIC INPUT.—**Prior to beginning negotiations with the regulated industry on the reauthorization of this part, the Secretary shall—*

(A) publish a notice in the Federal Register requesting public input on the reauthorization; (B) hold a public meeting at which the public may present its views on the reauthorization, including specific suggestions for changes to the goals referred to in subsection (a); (C) provide a period of 30 days after the public meeting to obtain written comments from the public suggesting changes to this part; and (D) publish the comments on the Food and Drug Administration's Internet Web site.

***(3) PERIODIC CONSULTATION.**—Not less frequently than once every month during negotiations with the regulated industry, the Secretary shall hold discussions with representatives of patient and consumer advocacy groups to continue discussions of their views on the reauthorization and their suggestions for changes to this part as expressed under paragraph (2).*

***(4) UPDATES TO CONGRESS. —**The Secretary, in consultation with regulated industry, shall provide regular updates on negotiations on the reauthorization of this subpart to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives.*

(5) PUBLIC REVIEW OF RECOMMENDATIONS.*—After negotiations with the regulated industry, the Secretary shall— (A) present the recommendations developed under paragraph (1) to the Congressional committees specified in such paragraph; (B) publish such recommendations in the Federal Register; (C) provide for a period of 30 days for the public to provide written comments on such recommendations; (D) hold a meeting at which the public may present its views on such recommendations; and (E) after consideration of such public views and comments, revise such recommendations as necessary.*

***(6) TRANSMITTAL OF RECOMMENDATIONS.—**Not later than January 15, 2027, the Secretary shall transmit to the Congress the revised recommendations under paragraph (4), a summary of the views and comments received under such paragraph, and any changes made to the recommendations in response to such views and comments.*

(7) MINUTES OF NEGOTIATION MEETINGS.—

***(A) PUBLIC AVAILABILITY.—**The Secretary shall make publicly available, on the public Web site of the Food and Drug Administration, minutes of all negotiation meetings conducted under this subsection between the Food and Drug Administration and the regulated industry, not later than 30 days after each such negotiation meeting..*

***(B) CONTENT.**—The minutes described under subparagraph (A) shall summarize, in sufficient detail, any substantive proposal made by any party to the negotiations as well as significant controversies or differences of opinion during the negotiations and their resolution.*

Today's meeting begins the stakeholder consultation process.

Initial Public Meeting & Public Comment

Today – Public comment period closes January 2, 2026

> ***(2) PRIOR PUBLIC INPUT.***—*Prior to beginning negotiations with the regulated industry on the reauthorization of this part, the Secretary shall—*
>
> *(A) publish a notice in the Federal Register requesting public input on the reauthorization; (B) hold a public meeting at which the public may present its views on the reauthorization, including specific suggestions for changes to the goals referred to in subsection (a); (C) provide a period of 30 days after the public meeting to obtain written comments from the public suggesting changes to this part; and (D) publish the comments on the Food and Drug Administration's Internet Web site.*

Public Stakeholder Meetings

Monthly during negotiations – sign-up by January 30, 2026

> ***(3) PERIODIC CONSULTATION.***—*Not less frequently than once every month during negotiations with the regulated industry, the Secretary shall hold discussions with representatives of patient and consumer advocacy groups to continue discussions of their views on the reauthorization and their suggestions for changes to this part as expressed under paragraph (2).*

Public Minutes from FDA-Industry Negotiation Meetings

Posted within 30 days of each meeting

> *(**A) PUBLIC AVAILABILITY.**—The Secretary shall make publicly available, on the public Web site of the Food and Drug Administration, minutes of all negotiation meetings conducted under this subsection between the Food and Drug Administration and the regulated industry, not later than 30 days after each such negotiation meeting..*

Industry Perspective

Industry Perspective

Juliana Reed

The Biosimilars Forum

Executive Director

Biosimilars: Safe, Effective, Lower-Cost Medicines

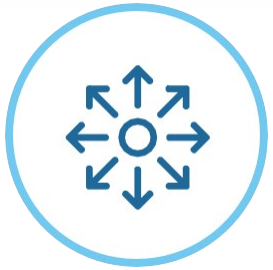
Juliana M. Reed
Executive Director - Biosimilars Forum

Biosimilars FORUM

The Biosimilars Forum

We are a nonprofit dedicated to expanding patient access to life-saving biosimilar drugs. We work with policymakers and stakeholders to create public policies that encourage biosimilar awareness and education and increased use.

Lower prescription drug costs for millions of Americans that need them



Increase access to lifesaving, lower-cost treatments

Educate patients, providers, employers, and payers on the safety and efficacy of biosimilars

Engage with the Administration and lawmakers to implement policies that promote biosimilars

Work with regulatory bodies to advance biosimilars

Biosimilars FORUM


amneal
PHARMACEUTICALS


teva


SANDOZ


meitheal
Generics | Biologics | Biosimilars


SAMSUNG
BIOEPIS


Pfizer


Henlius


ORGANON


Biocon Biologics

Thank You to Commissioner Makary and the entire FDA team!

OPINION

DR. MAKARY, DR OZ: People talk about lowering healthcare costs, but the Trump administration is doing it

FDA removes extra clinical trial requirements for biosimilar medications that cost up to $200,000 annually

By **Dr. Marty Makary** , **Dr. Mehmet Oz** **OPINION** **Fox News**

Published November 3, 2025 7:00am EST

Celebrating 10 years of Biosimilars in the US

The first biosimilar was approved in the United States in 2015, almost 10 years after physicians in Europe began using them.

Fifteen years ago, Congress passed the landmark Biologics Price Competition and Innovation Act (BPCIA) to pave the way for biosimilars to lower drug costs for Americans.

Since the first biosimilar was approved in 2015 by the FDA, more than 70 biosimilars have been approved and saved the U.S. healthcare system. In Europe, nearly 120 biosimilars have been approved.

Biosimilars Competition is the Solution to Lowering Prescription Drug Prices

Americans are facing a healthcare crisis. Patients should never have to choose between their health and financial security. Unfortunately, this occurs across America. Nearly **30% of Americans say they haven't taken their medication as prescribed due to unaffordable prices.**

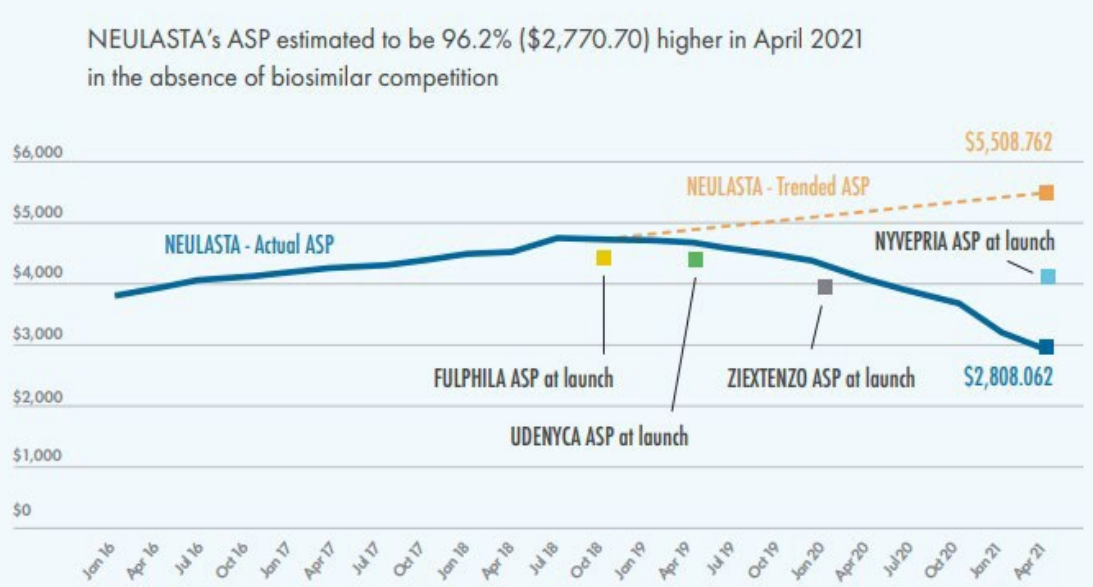
President Trump, his Administration, and the FDA have an opportunity to deliver a commonsense, free market-driven solution to lower out-of-control prescription drug prices by making lower-cost biosimilars more accessible to patients that need them.

In the last ten years, biosimilars have been associated with savings of **$56 billion** compared to what spending would have been without biosimilars. The next five years could see an increase in savings up to **$181 billion** as newly approved biosimilars launch and existing biosimilars see continued uptake.

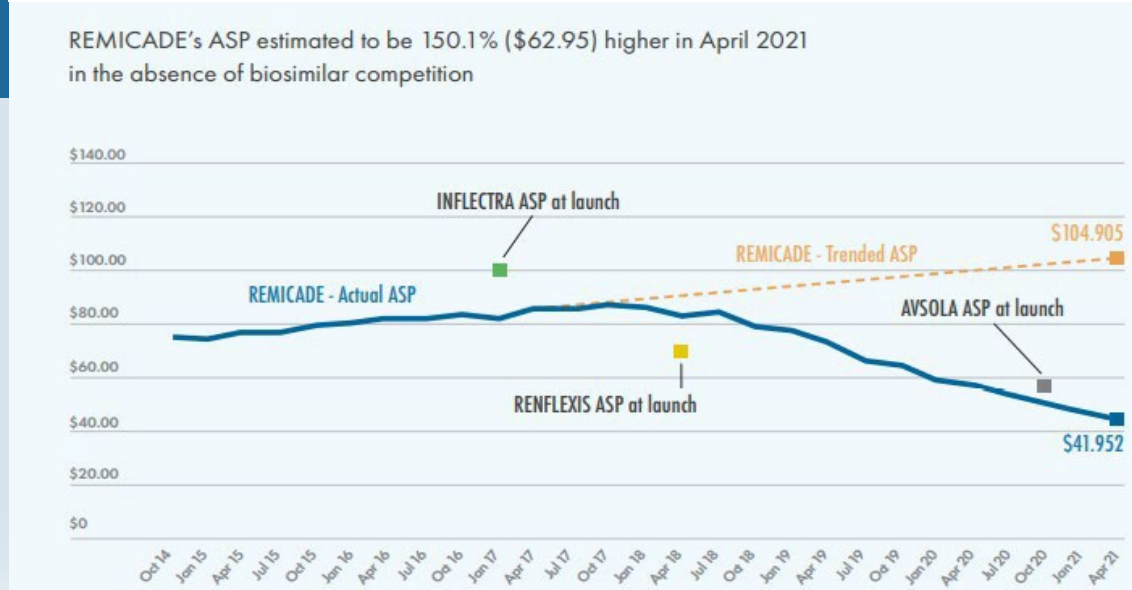
Biosimilars Lower the Cost of Treatment

When a biosimilar enters the market, it lowers the ASP of its reference biologic

Neulasta's Actual ASP and Trended ASP Without Biosimilars



REMICADE's Actual ASP and Trended ASP Without Biosimilars



Xcenda Research. https://biosimilarsforum.org/wp-content/uploads/Xcenda-ASP-One-Pager.pdf

Biosimilars FORUM

There Is a Significant Biosimilars Void in U.S.

Over the next decade, 118 biologics are expected to lose patent protection. This includes a significant wave of oncology drugs.

Biosimilars could offer significant cost-savings for each of these.

Unfortunately, only 10% currently have biosimilars in development, while 90% have no biosimilar in the pipeline. This void in the biosimilar market significantly limits savings potential for Americans.

Barriers to access must be addressed to ensure the biosimilar pipeline continues.

A Viable Market for Biosimilars Is Necessary to Ensure the Development Costs

To ensure the sustainability of the biosimilar market and the savings and affordability benefits are fully realized by the healthcare system and patients, barriers to access must be addressed.

Unfortunately, biosimilar competition is not a certainty for all biologics. Increasing pressures on biosimilar developers and barriers to access continue to limit the future cost-savings potential of biosimilars.

Factors limiting biosimilar development include burdensome regulatory requirements, slow market adoption, high investment costs, confusion over interchangeability, reimbursement challenges, and uncertainty related to the Inflation Reduction Act.

Understanding Biosimilar Development

The biosimilar development, approval, and launch process focuses on efficacy and safety for patients.

Biosimilar development can take between 6-9 years and can cost up to $300 Million

FDA review and approval can take 12 months or longer

The FDA BsUFA III Regulatory Science Roadmap was a start to achieving streamlined development

Source: FDA

Biosimilars Forum Supports a Strong, Efficient and Well-Resourced FDA

The FDA and the people who work here are champions that work hard to ensure the safety and efficacy of the medicines we take as Americans.

Everywhere in this country, every time a physician prescribes a medicine, or you take a medicine or perhaps your children or your elderly parents take their medicine, the people in who work for the FDA around the world work with one common goal: to ensure our health and safety.

A strong and well-resourced FDA is essential to do this.

There is always an opportunity to revisit old policies and procedures and to update them based on new science, new knowledge and greater experience.

BsUFA IV is that opportunity.

It's time to build on our 10 years of biosimilar development and review in the US

BsUFA IV is our opportunity as industry to work with the FDA to acknowledge our collective experience and expertise in the development of biosimilars.

We have gained scientific expertise, developed new technologies, and have launched biosimilars not only here in the US, but around the world.

We need to acknowledge our gains in experience and work together to adapt the FDA process for the development and review of biosimilar applications.

We should come prepared to ask ourselves as industry and FDA:

- What have we learned, what is the most efficient way to review a biosimilar application within the Agency?
- What is necessary and unnecessary after 10 years?
- What can we change?
- How can we support new processes that will allow US patients to have biosimilars of products that today are members of the biosimilars void?

Thank you!

Questions?

Biosimilars FORUM

Industry Perspective

Scott Kuzner

Biosimilars Council

Senior Director, Sciences and Regulatory Affairs

Industry Perspective

Sean Hilscher

PhRMA

Senior Director, Science and Regulatory Advocacy

PhRMA
RESEARCH • PROGRESS • HOPE

Public Meeting on the Reauthorization of the Biosimilar User Fee Act (BsUFA)

December 3, 2025

Biosimilars Help Bring New Treatment Options to Patients and Increase Competition in the Market

- PhRMA supports advancing policies that promote innovation and competition in the biologics and biosimilars marketplace
- As America's health care system continues to evolve, biosimilars continue to play an increasingly critical role in bringing new options to patients and increasing competition
- The development and approval of safe and effective biosimilars depends upon a U.S. regulatory framework that supports timely, science-based decision-making

PhRMA
RESEARCH • PROGRESS • HOPE

BsUFA Plays an Important Role in Helping Increase Timely Patient Access to Safe and Effective Biosimilars

Since 2012, user fee resources provided through the Biosimilars User Fee Act (BsUFA) have helped enhance the consistency and predictability of the FDA's review of biosimilar products by:

- **Establishing review timelines and enhancing review processes** to provide patients and sponsors with greater predictability
- **Enabling timely, consistent, and meaningful communication** between FDA and sponsors during the regulatory review
- **Strengthening scientific dialogue** between sponsors and the FDA

PhRMA
RESEARCH • PROGRESS • HOPE

BsUFA IV Can Continue to Support FDA's Vital Role in Medical Product Review and Protecting the Public Health

BsUFA IV can build on previous BsUFA agreements to help ensure review processes are consistent, predictable, transparent, and rooted in sound scientific principles.

- Responsive
- Transparent
- Accountable
- Efficient
- Independent and Science-Based

PhRMA
RESEARCH • PROGRESS • HOPE

BsUFA IV Should Focus on Core Review Functions to Continue to Ensure Timely Access to Biosimilars

BsUFA IV offers FDA the opportunity to enhance and further support biosimilar product development and increase review efficiency by:

- Improving review times to ensure U.S. patients have timely access to biosimilars and ultimately benefit from increased competition in the marketplace
- Ensuring that review process enhancements introduced in prior BsUFA cycles are utilized effectively
- Enhancing timelines and communication between FDA and biosimilar applicants

PhRMA
RESEARCH • PROGRESS • HOPE

BsUFA IV Should Enhance the Financial Stability and Sustainably of the Program

- BsUFA IV should streamline the financial structure of the program to be consistent with the current resource needs of the Agency

- Simplifying the user fee revenue process would result in greater predictability for FDA and industry

- By matching resources with programmatic needs, FDA can better plan for the future and ensure the sustainability of the program

PhRMA
RESEARCH • PROGRESS • HOPE

Conclusion

- BsUFA IV should help ensure FDA has the resources to support science-based review of biosimilars, which will help increase competition in the marketplace to the benefit of patients
- PhRMA looks forward to working collaboratively with FDA, patient groups and other stakeholders to continue the progress that has been achieved and make enhancements where appropriate in BsUFA IV
- A timely reauthorization of the user fee program is imperative to avoid any unnecessary disruptions and to fully realize the potential of the improvements that will be included
- Ensuring that the U.S. biosimilar review pathway remains properly resourced—through a combination of Congressional appropriations and industry user fees—will help support the next generation of safe, potent, and pure biosimilars products

U.S. FOOD & DRUG ADMINISTRATION

BREAK

Check the Q&A for our restart time.

Public Comment

Closing Remarks

Jonathan Collins

Center for Drug Evaluation and Research, FDA

Meeting Moderator, Program Evaluation and Implementation Staff,
Office of Program and Strategic Analysis, Office of Strategic Programs

Submit your public comments by January 2nd!

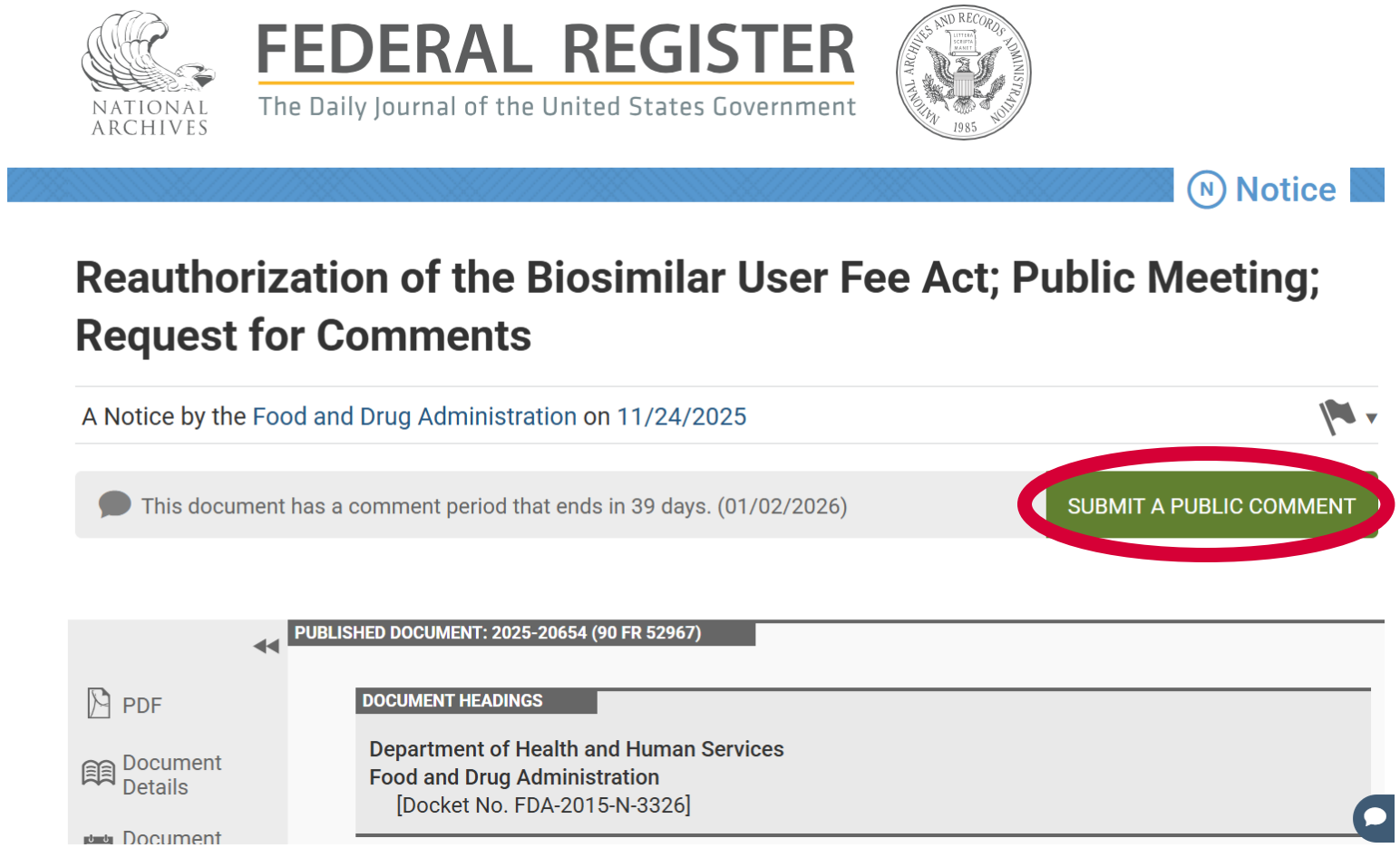
You can access the docket via:

- FDA's public meeting webpage

  (https://www.fda.gov/industry/public-meeting-reauthorization-biosimilar-user-fee-act-bsufa-12032025)

- Directly through the Federal Register

  (https://www.federalregister.gov/documents/2025/11/24/2025-20654/reauthorization-of-the-biosimilar-user-fee-act-public-meeting-request-for-comments)



U.S. FOOD & DRUG ADMINISTRATION

THANK YOU