WELCOME

We'll begin promptly at 9:00 am (ET).

FDA U.S. FOOD & DRUG ADMINISTRATION

Public Meeting on the Prescription Drug User Fee Act and Biosimilar User Fee Amendments Hiring and Retention Assessment

Wednesday, September 24th, 2025

Welcome and Introduction

Thamar Bailey

Center for Drug Evaluation and Research, FDA

Program Evaluation and Implementation Staff, Office of Strategic Programs

Agenda

- Welcome and Introduction
- Presentation of the Assessment
- Break
- FDA Perspective
- Public Comments
- Closing Remarks

Submit your public comments by October 24!

You can access the docket via:

- FDA's public meeting webpage (https://www.fda.gov/drugs/news-events-human-drugs/prescription-drug-user-fee-act-and-biosimilar-user-fee-amendments-hiring-and-retention-assessment)

- Directly through the Federal Register (https://www.federalregister.gov/documents/2025/08/25/2025-16245/prescription-drug-user-fee-act-and-biosimilar-user-fee-amendments-hiring-and-retention-assessment)

FEDERAL REGISTER
The Daily Journal of the United States Government
NATIONAL ARCHIVES

Ⓝ Notice

Prescription Drug User Fee Act and Biosimilar User Fee Amendments Hiring and Retention Assessment; Public Meeting; Request for Comments

A Notice by the Food and Drug Administration on 08/25/2025

💬 This document has a comment period that ends in 60 days. (10/24/2025)   SUBMIT A PUBLIC COMMENT

PUBLISHED DOCUMENT: 2025-16245 (90 FR 41395)

📄 PDF

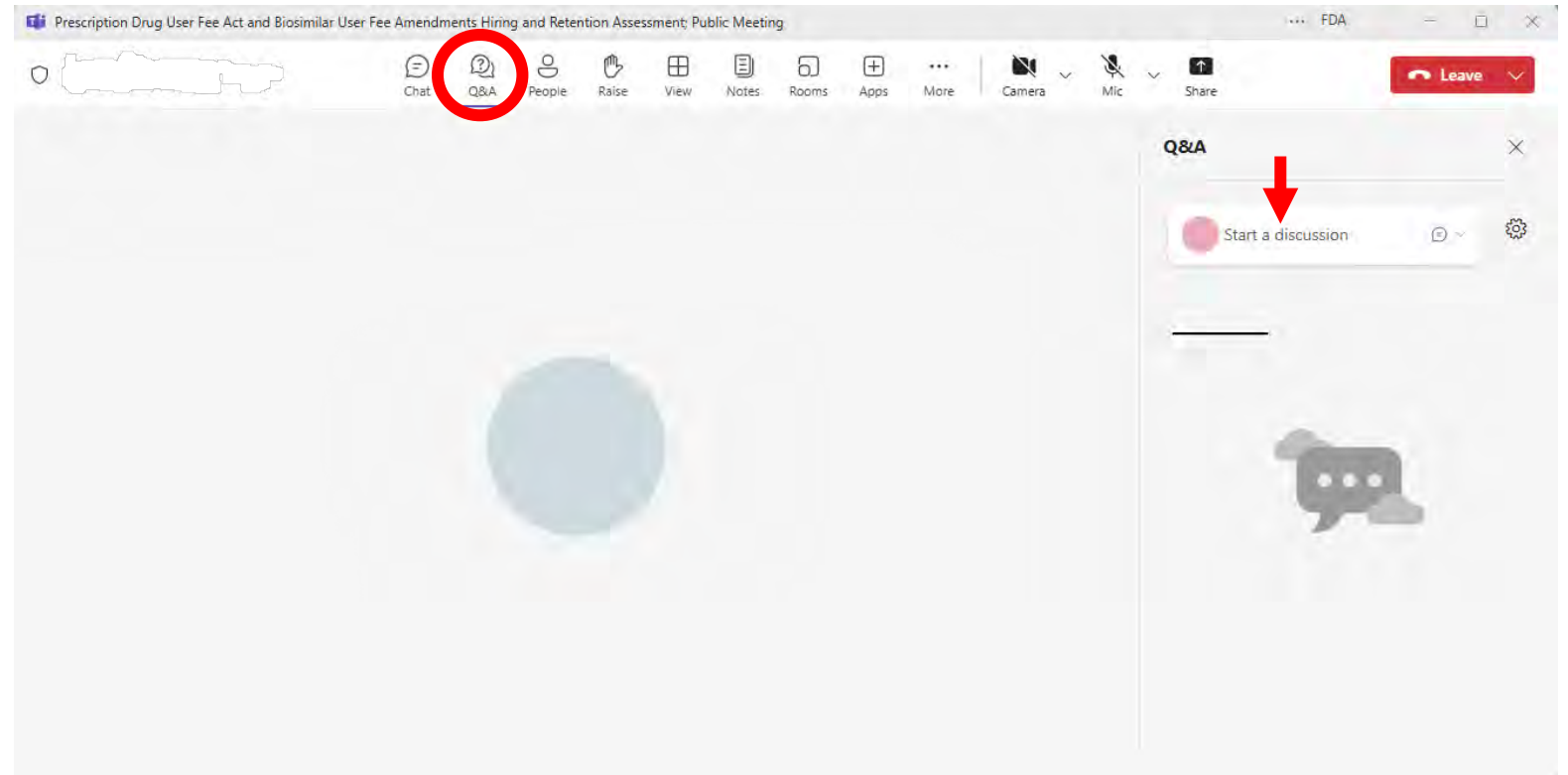📖 Document Details

DOCUMENT HEADINGS

Department of Health and Human Services
Food and Drug Administration
[Docket No. FDA-2025-N-2962]

💬 Site Feedback

Technical issues during the meeting?

- Send a message through the Q&A in Teams

- Email your issue to CDERProgramEvaluation@fda.hhs.gov

Presentation of the Assessment

Valerie Overton

Vice President, Eastern Research Group

PDUFA/BsUFA Hiring and Retention Assessment

Public Meeting Presentation

September 24, 2025

Presentation Outline

- Introduction

  - Key Objectives

  - Assessment Questions

  - Methods

- Answers to Assessment Questions

- Findings and Recommendations

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Introduction

Key Objectives (KOs) of Evaluation

> This third-party independent assessment is an FDA commitment for PDUFA VII and BsUFA III. The commitment letter alongside input from FDA leadership informed the key objectives.

KO1: Document and analyze **enhancements** made to FDA's human drug review program in hiring and retention since final PDUFA VI assessment

KO2: Build on previous assessments to capture **current status** of FDA's recruiting, hiring, pre-employment onboarding, and retention of new hires and **effectiveness of current practices**

KO3: Assess **transparency** in hiring process from the perspective of interested parties

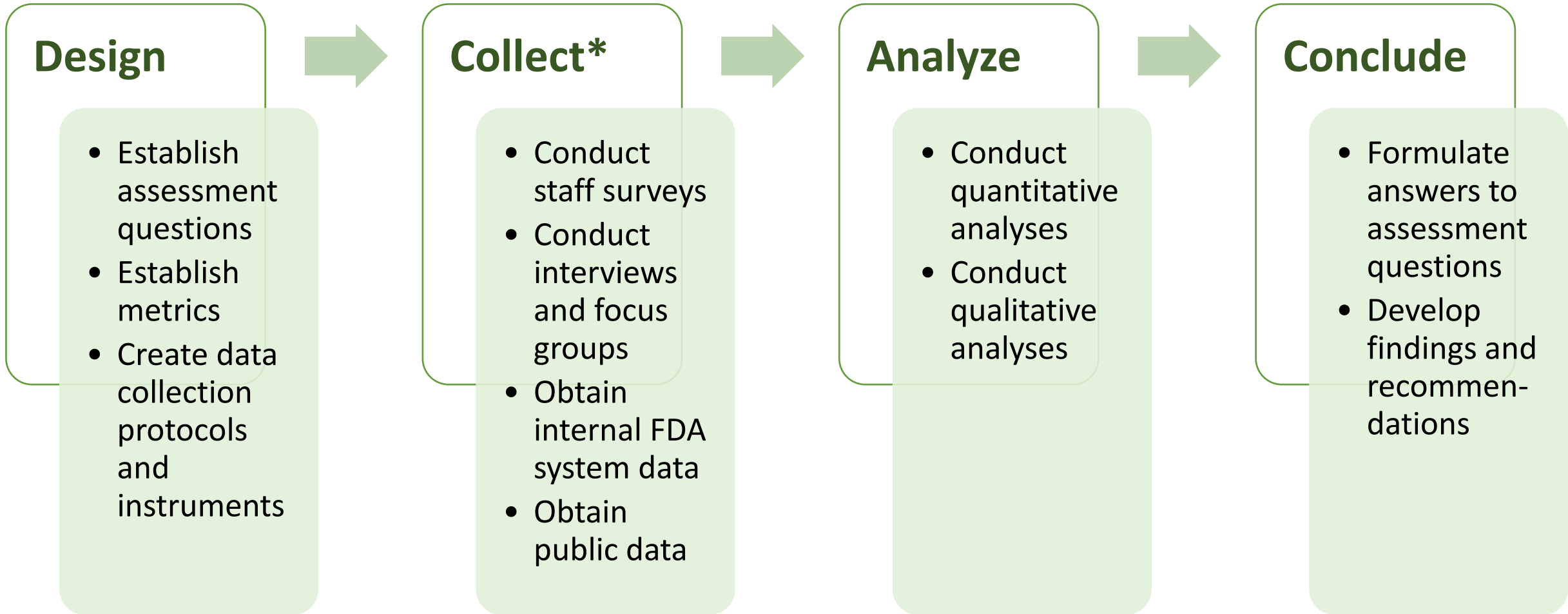PDUFA = Prescription Drug User Fee Act. BsUFA = Biosimilar User Fee Amendments.

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Assessment Questions

> ERG addressed three to five assessment questions per key objective.

Key Objective 1	Key Objective 2	Key Objective 3
• What is the status of planned enhancements? • What caused implementation delays? • To what extent were enhancements implemented with fidelity? • What is the impact on hiring and retention outcomes?	• What is the current status of FDA recruiting? • What is the current status of FDA hiring? • What is the current status of FDA onboarding? • What is the current status of retention of new hires? • How do outcomes compare to similar agencies and industry?	• Are hiring processes clear to FDA HR/HC staff? • How transparent is hiring to other FDA staff? • How transparent is hiring to new staff?

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Methods

Design → **Collect*** → **Analyze** → **Conclude**

Design
- Establish assessment questions
- Establish metrics
- Create data collection protocols and instruments

Collect*
- Conduct staff surveys
- Conduct interviews and focus groups
- Obtain internal FDA system data
- Obtain public data

Analyze
- Conduct quantitative analyses
- Conduct qualitative analyses

Conclude
- Formulate answers to assessment questions
- Develop findings and recommen-dations

*Findings reflect data collected October 2, 2023 to January 31, 2025.

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Answers to Assessment Questions

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KO1: HR/HC Program Enhancements

- **HR data systems (ATLAS, AOIS, PathHR).** ATLAS tracks Agency-wide OTS hiring processes, while AOIS (CDER) and PathHR (CBER) handle Center-specific HR activities for human drug review staff.

- **Integrated HR/HC service delivery model.** This model seeks to integrate HR processes across the full HR workforce to streamline and enhance workforce planning, recruitment, development, and retention efforts across FDA.

- **Leadership succession planning.** This planning seeks to manage (and mitigate) the potential impacts of attrition among senior FDA leaders.

ATLAS = Applicant Tracking Lifecycle Analysis Solution. AOIS = Administrative Operations Information System. OTS = Office of Talent Solutions. CDER = Center for Drug Evaluation and Research. CBER = Center for Biologics Evaluation and Research. HR/HC = Human Resource/Human Capital.

KO1: Status and Impacts of HR Data System Enhancements

> FDA's HR data system enhancements have modernized and streamlined HR processes, improving efficiency and transparency.

Status	Fully implemented	✓ FDA implemented all planned enhancements ✓ FDA continues to refine the systems based on user feedback
Delays	No significant delays	✓ FDA implemented most enhancements on schedule
Fidelity	Aligns with goals	✓ FDA's implementation closely aligns with stated goals
Impacts	Positive impacts	✓ Automate and streamline previously manual processes ✓ Provide real-time data for status checking and decision-making ✓ Decrease in average time to complete the portion of the hiring process tracked in ATLAS for PDUFA / BsUFA employees ➢ Some users would like more integrations and broader access

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KO1: Status and Impacts of Integrated Service Delivery Model

> FDA's HR/HC Integrated Service Delivery model fosters a more unified, collaborative approach with improved skill building and data.

Status	Fully implemented	✓ Planned initiatives and action items are complete or on track
Delays	No significant delays	✓ FDA has adjusted its strategy to address potential delays
Fidelity	Aligns with goals	✓ FDA's implementation closely aligns with stated goals
Impacts	Positive impacts	✓ Improved training, development, and engagement ✓ Improved collaboration (though further improvement desired) ✓ Improved data analytics and integration to support decision-making ✓ Expanded use of Title 21 to increase hiring flexibility and competitiveness

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KO1: Status and Impacts of Leadership Succession Planning

> FDA's leadership succession planning initiatives have helped identify risks and strengthen the Agency's leadership pipeline.

Status	Fully implemented	✓ Planned initiatives and action items are complete or on track
Delays	No significant delays	➤ Center-level planning challenged by unexpected vacancies and resource limitations
Fidelity	Aligns with goals	✓ Implementation aligns with strategic priorities and supports workforce initiatives
Impacts	Positive impacts	✓ Trainings and programs available to develop needed skills ✓ Agency-level planning provides guidance for Center-level activities ✓ Reports and analytics to identify succession planning challenges

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KO2: Current State of FDA Recruiting

➤ FDA's current practices yield a sufficient talent pool to produce skilled, qualified hires that meet CDER and CBER staffing needs.

Successes	Remaining Challenges

Successes

- ✓ Expanded use of Title 21 (makes FDA more competitive)

- ✓ Outreach at conferences and hiring events; use of social media; strategic partnerships

- ✓ HR/HC staff satisfaction with recruitment processes they control

- ✓ New hire satisfaction with recruitment process and decision to work at FDA

Remaining Challenges

- ➤ Occasional OTS-Center disagreements about whether candidates are qualified for position, leading to inefficiencies

- ➤ Limited mechanisms for potential applicants to learn about Title 21 (primarily word of mouth and LinkedIn), though piloting expanded announcement process

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KO2: Current State of FDA Hiring

> FDA's current practices appropriately evaluate candidates and identify future employees to support FDA's public health mission.

Successes

- ✓ Expanded use of Title 21 to streamline hiring

- ✓ Reduced time to complete steps tracked in ATLAS

- ✓ New hire satisfaction with hiring process

- ✓ Hiring manager satisfaction with processes under their control, OTS staff satisfaction with overall hiring process

- ✓ Standardized interviews and screening processes

OM = Office of Management.

Remaining Challenges

- ➤ Lengthy process (mostly outside FDA control), sometimes leading candidates to seek jobs elsewhere

- ➤ Center HR/HC staff concerns with length of certificate generation and tentative offer processes

- ➤ Some workflow gaps in HR data systems (e.g., lack of tracking mechanism for packages between Center OM and OTS)

- ➤ For Title 21, OTS qualification of candidate after selection (sometimes leads to inefficiencies if selectee deemed not qualified)

KO2: Current State of FDA Pre-employment Onboarding

➤ FDA's current practices lead to successful completion of security checks and ethics pre-clearances within expected timelines.

Successes

✓ Standardized, clear processes for responsible staff

✓ Timeliness of processes within staff control

✓ New hire satisfaction with processes

✓ New hire satisfaction with new employee orientation

Remaining Challenges

➢ Some confusion about who is responsible for initiating security and ethics clearances

➢ Delays outside FDA control (e.g., lack of timely submission of paperwork by candidates)

KO2: Current State of FDA Retention

> Through FY2024, FDA's retention practices have contributed to high retention rates (low attrition rates).

Successes

- ✓ New hire satisfaction with decision to work in current position and Center

- ✓ Staff appreciation of FDA mission (key retention factor)

- ✓ Agency-level HR/HC staff satisfaction with work-life balance and programs (retention factor)

- ✓ OTS and OHCM staff satisfaction with HR/HC culture

- ✓ Telework and work schedule flexibility

Remaining Challenges

- ➢ Staff desire for more growth opportunities

- ➢ Difficulty competing with industry salaries (mostly outside FDA control)

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KO2: FDA Outcomes Compared to Other Agencies and Industry

> FDA performs comparably across most outcomes and has better retention rates.

Successes

✓ FDA's HR/HC structure and practices comparable to those of similar agencies

✓ FDA outcomes comparable to similar agencies and industry in terms of length of service and accession rates

✓ FDA (CDER/CBER) retention rates somewhat higher than similar agencies and substantially higher than industry

Remaining Challenges

➤ Despite improved time to hire and salary flexibility (with Title 21), industry can hire more quickly and at higher salaries (outside FDA control)

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KO3: Transparency of FDA Hiring to HR/HC Staff

> Roles, processes, communication, and collaboration are clear within an organizational unit, but sometimes less clear across units.

Successes	Remaining Challenges

Successes

- ✓ Clarity of roles and availability of resources within organizational unit

- ✓ Status tracking and action ownership (improved transparency) with use of enhanced HR data systems

- ✓ Regular meetings about shared processes

Remaining Challenges

- ➢ Insufficient or untimely communication about policy and process changes

- ➢ Some lack of clarity about cross-Office points of contact, communication, and collaboration

- ➢ Some gaps in HR data system workflows/ integration and access

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KO3: Transparency of FDA Hiring to Other FDA Staff

> Hiring managers understand their roles and appreciate status tracking with data systems but could benefit from improved communication.

Successes

- ✓ Clarity of roles and availability of resources within organizational unit

- ✓ Status tracking and action ownership (improved transparency) with use of enhanced HR data systems

- ✓ Regular meetings about shared processes

Remaining Challenges

- ➢ Insufficient or untimely communication about policy and process changes

- ➢ Some lack of clarity about cross-Office points of contact, communication, and collaboration (sometimes impacted candidate retention during hiring process)

- ➢ Some hiring managers express concerns about HR system data accuracy, access, and timing in the hiring process

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KO3: Transparency of FDA Hiring to New Staff

> While progress has been made, CDER and CBER new hires still have mixed experiences with hiring process transparency.

Successes

✓ Some progress on hiring process transparency

Remaining Challenges

➢ New hires considered other jobs due to uncertainty of hiring status and timeline

➢ Contradictory information or multiple requests for information (by different HR staff) sent to candidates

➢ New hire perception that salary would be higher in another Office or Center

Findings and Recommendations

HR/HC Overall

	Finding	Recommendation(s)
⬆	FDA's HR program has improved. FDA attracts and retains qualified staff.	None.
⬆	Due to its flexibilities, Title 21 hiring authority is attractive to both candidates and FDA staff.	None.
➡	Communication and coordination across Offices and Centers continue to be a pain point.	• Clarify roles and touchpoints for processes that require cross-unit coordination. • Consistently communicate and document policy and process changes directly to affected staff; have changes take effect at predictable points. • Explore further HR data system integrations and various types of access.

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HR Enhancements

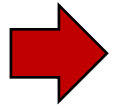| Finding	Recommendation(s)
FDA has successfully implemented each enhancement area with minimal to no delays and in alignment with stated goals.	For HR data systems, continue to implement updates and address missing or unintegrated workflows (including process that span Offices and Centers) and expand access for more staff in more roles where feasible.

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HR Practices

Finding	Recommendation(s)
FDA recruitment and outreach strategies are effective in making opportunities visible to prospective applicants.	None.
FDA's hiring process is effective. Good practices promote fair, consistent treatment of candidates. Staff sometimes experience challenges with (1) which candidates are deemed qualified on certificates, and (2) confusion about who is responsible for initiating security and ethics pre-clearance processes.	• Expand standardized screening and interview practices. • Address qualifications procedures to ensure hiring managers and OTS HR specialists share common understanding about which candidates can be considered qualified. • Clarify roles and responsibilities for security and ethics pre-clearances initiation across all involved parties.

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HR Practices (continued)

Finding	Recommendation(s)
Due to hiring process length and insufficient communication, FDA loses some qualified candidates.	Add touchpoints with candidates to communicate status and express appreciation for patience.
Agency- and Center-specific new employee orientations are effective in preparing staff to begin work at FDA.	None.
Most new hires are satisfied with the decision to work in the current position and Center.	None.
FDA's retention initiatives are largely effective, but some challenges exist.	To the extent possible, continue or re-establish valued retention initiatives, create and publicize leadership development and promotion opportunities, and convert employees to Title 21.

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HR Practices (continued)

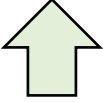| Finding	Recommendation(s)
FDA's data on time to hire exist in disparate systems, making it difficult to accurately calculate total time to hire. Within specific elements of the hiring process, FDA generally meets SLAs.	• Investigate mechanisms to calculate total time to hire across disparate systems and identify data for individual process phases. • Analyze factors contributing to total time to hire beyond current SLAs and identify opportunities to reduce overall hiring timelines.

SLA = Service Level Agreement.

Transparency

Finding	Recommendation(s)
⬆ New hires are generally satisfied with hiring process and decision to join FDA, but lack of transparency about status sometimes causes them to seek employment elsewhere.	As described above, add touchpoints to communicate status and next steps.
⬆ Staff involved in hiring generally understand their own roles and processes, but do not consistently find roles and processes in other Offices and Centers to be transparent.	As described above, clarify cross-unit communication and coordination.
⬆ FDA's HR data systems have greatly improved the transparency of hiring actions and statuses; opportunities for improvement still exist.	As described above, continue to add workflows and expand access to more staff.

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Closing

- For more information, see the **PDUFA VII/BsUFA III Hiring and Retention Assessment Final Report**

- FDA is accepting public comments until **October 24th, 2025**

BREAK

We will resume at 10:05 AM

FDA Perspective

Reductions, Shared Services, and the Path Forward

Office of the Commissioner

Melanie Keller, MBA | Deputy Chief Operating Officer, Office of Operations

Chantal Dawson, MBA | Acting Chief Talent Officer, Office of Operations

FDA Hiring Landscape - 2025

January 21st, 2025, Governmentwide hiring freeze.

The second extension of the freeze expires October 15th, 2025

In 2025, the FDA underwent significant organizational restructuring and HR reductions due to governmentwide hiring freeze and HHS Reduction in Force (RIF).

~30% reduction in Office of Talent and Human Capital Management

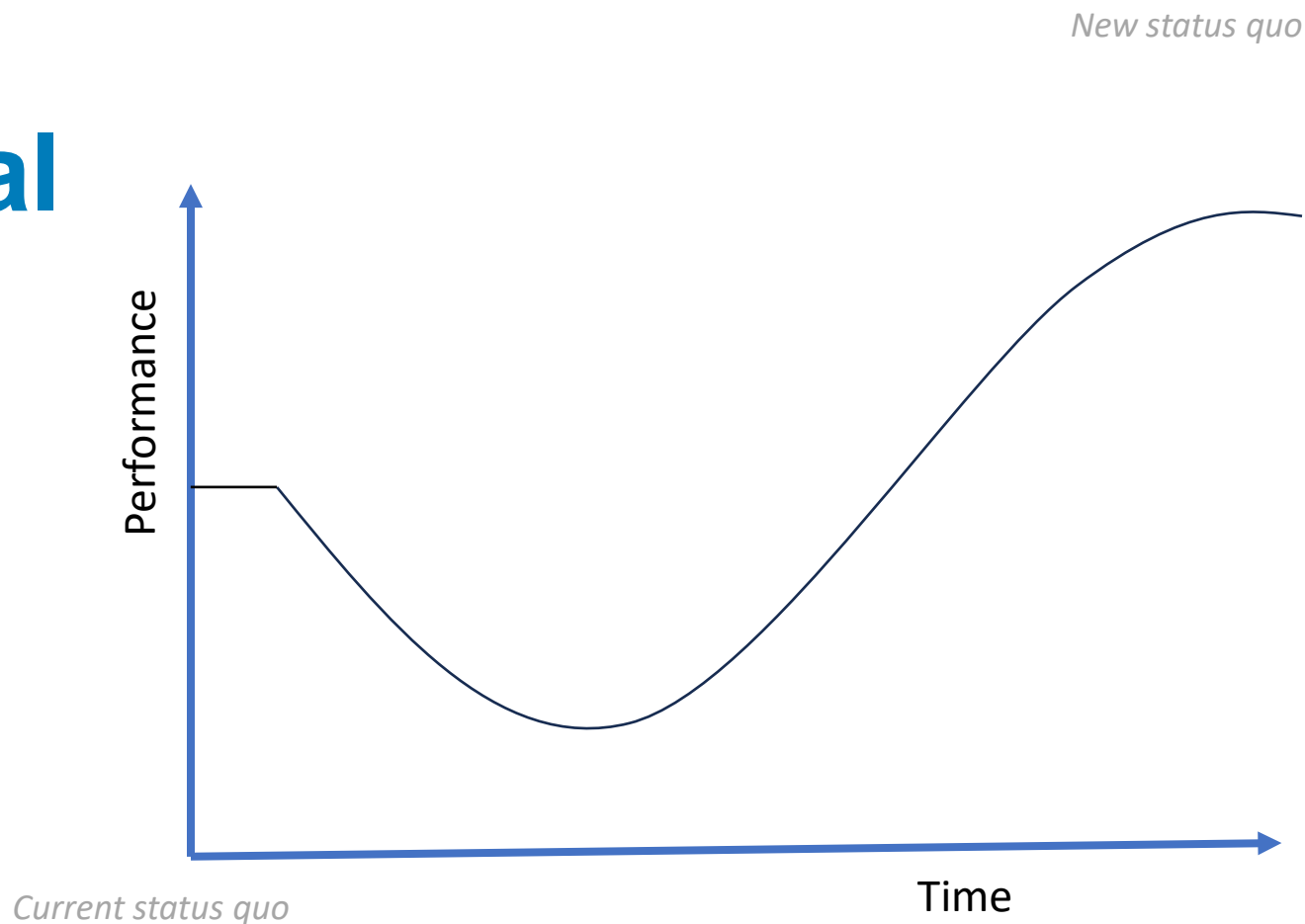Eliminated CDER and CBER Offices of Management

Additional Workforce Departures

Deferred Resignation Program (DRP)

Voluntary Early Retirement/Voluntary Separation Incentives

Retirements

Impacts of Organizational Change

FDA's transformation demonstrates that while workforce reductions, hiring freezes, and restructuring create short-term declines, centralized shared services and streamlined HR processes enable recovery and drive long-term improvement.

Performance

Time

Current status quo

Centralized Shared Services

Centralized HR services implemented at FDA level.

Direct HR staff to hiring manager connection.

Remaining CBER and CDER staff have been detailed to OO to provide HR support.
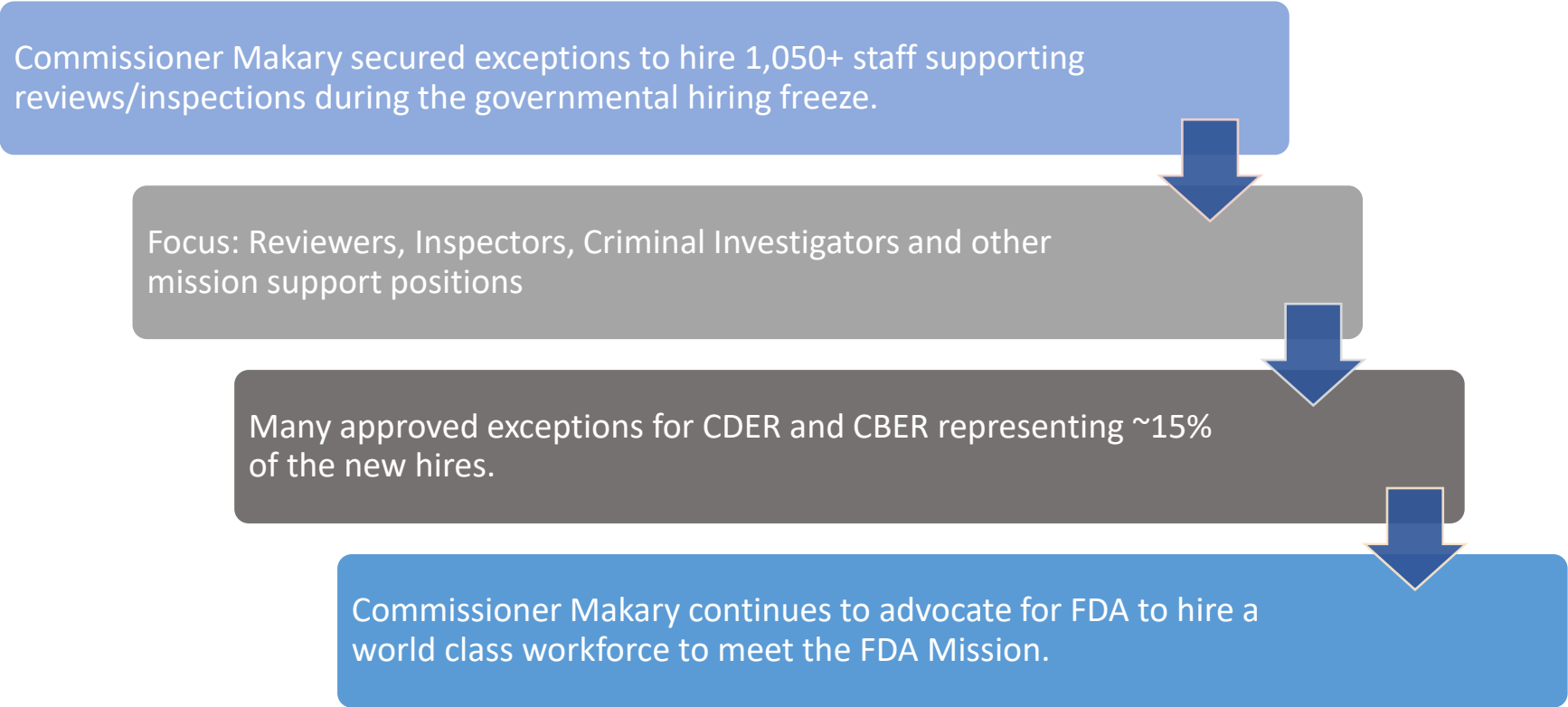
Eliminated 2-4 steps in the hiring approval process.

Leveraging IT innovation to improve efficiency.

Hiring Moving Forward

Commissioner Makary secured exceptions to hire 1,050+ staff supporting reviews/inspections during the governmental hiring freeze.

Focus: Reviewers, Inspectors, Criminal Investigators and other mission support positions

Many approved exceptions for CDER and CBER representing ~15% of the new hires.

Commissioner Makary continues to advocate for FDA to hire a world class workforce to meet the FDA Mission.

Recommendations

Evaluate and determine which recommendations to adopt within the context of the new centralized shared services model.

Public Comments

Juliana Reed

Biosimilars Forum

Janet Krommes

Doctors for America

Closing Remarks

Thamar Bailey

Center for Drug Evaluation and Research, FDA

Program Evaluation and Implementation Staff, Office of Strategic Programs

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THANK YOU