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ADMINISTRATION

WELCOME

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



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Public Meeting on the Recommendations and Proposed Enhancements for PDUFA VIII

Wednesday, September 16, 2026



Nana Adjeiwaa-Manu

Center for Drug Evaluation and Research, FDA

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

Submit your public comments by October 16!

You can access the docket via:

- FDA's public meeting webpage

(<https://www.fda.gov/drugs/news-events-human-drugs/public-meeting-recommendations-reauthorization-prescription-drug-user-fee-act-pdufa-09162026>)

- Directly through the Federal Register

(<https://www.federalregister.gov/documents/2026/08/14/2026-16650/reauthorization-of-the-prescription-drug-user-fee-act-public-meeting-request-for-comments>)



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Notice

Reauthorization of the Prescription Drug User Fee Act; Public Meeting; Request for Comments

A Notice by the Food and Drug Administration on 08/14/2026

Comments on this document are being accepted at Regulations.gov.

SUBMIT A PUBLIC COMMENT

PUBLISHED DOCUMENT: 2026-16650 (91 FR 52702)

PDF

Document Details

Document Dates

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DOCUMENT HEADINGS

Department of Health and Human Services
Food and Drug Administration
[Docket No. FDA-2026-N-8163]

AGENCY:

AGENDA

- Welcome and Introduction
- Opening Remarks
- PDUFA Background and Overview of Recommendations
- **Pre-Market Review:** Proposed Enhancements
- **Post-Market Safety:** Proposed Enhancements
- **Break**
- **Chemistry, Manufacturing, and Controls:** Proposed Enhancements
- **Finance:** Proposed Enhancements
- **Other Topics:** Proposed Enhancements
- **Break**
- **Public Stakeholder Perspectives**
- Public Comment
- Closing Remarks



Grace Graham

Deputy Commissioner for Policy, Legislation, and International Affairs



PDUFA

Background and Reauthorization Process



Andrew Kish

Center for Drug Evaluation and Research, FDA

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



PDUFA Background

Before 1992, timeliness of FDA drug review was a big concern.

PDUFA I

- User fees added resources for more review staff to eliminate the backlog of overdue applications and improve review timeliness
- FDA agreed to meet specific performance goals

Result:

- More predictable, streamlined process
- Patients gained earlier access to new drugs and biologics approved since 1992
- Overall, clinical development time and average time to approval dropped since 1992

PDUFA introduced fees to help enhance the review process.

- Fee funds are added to 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 in “process for the review of human drugs”
 - 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.
- Experience: *Devil is in the Details*

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

Performance commitments and fee funding have evolved since 1992.

PDUFA (1993-1997) | Added funds for pre-market review; reduced backlog and set predictable timelines (goals) for review action

PDUFA II (FDAMA, 1998-2002) | Shortened review timelines, added review goals; added process and procedure goals; added funding

PDUFA III (BT Preparedness & Response Act, 2003-2007) | Significantly added funding; increased interaction in first review cycle (GRMPs); allowed limited support for post-market safety

PDUFA IV (FDAAA, 2008-2012) | Increased and stabilized base funding; enhanced pre-market review; modernized post-market safety

PDUFA V (FDASIA, 2013-2017) | Small increase to base funding; review enhancements increased communication with sponsors; strengthened regulatory science & post-market safety; set electronic data standards

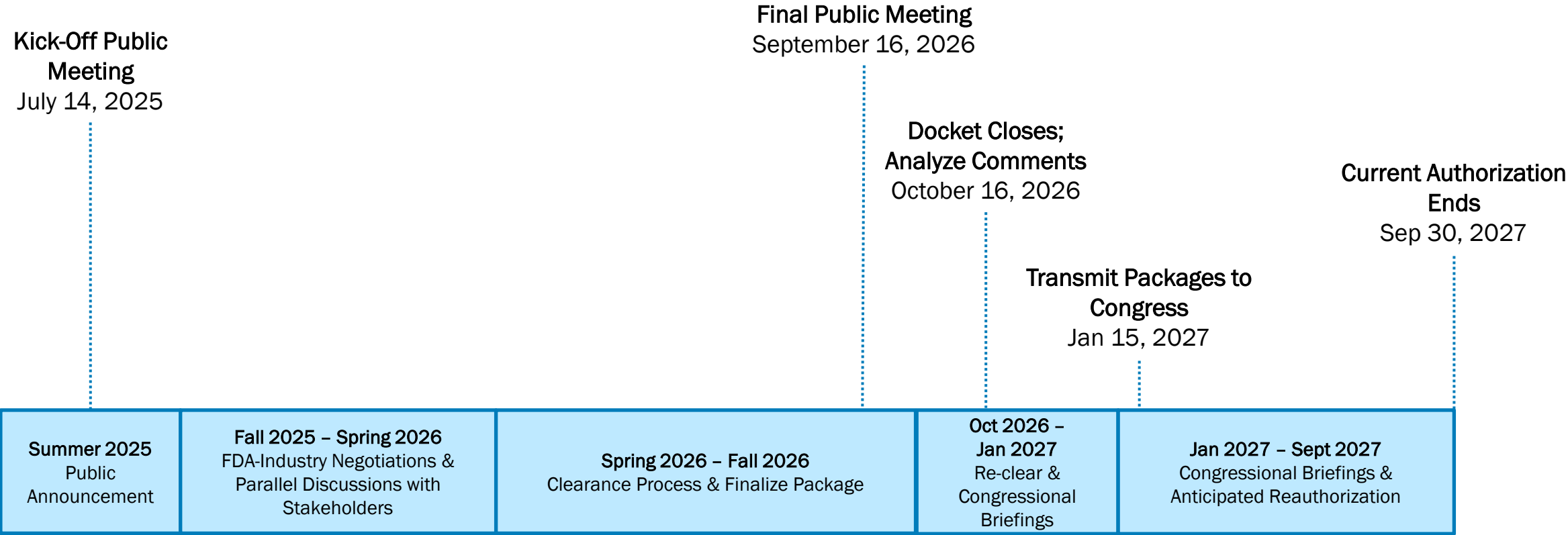
PDUFA VI (FDARA, 2018-2022) | Modernized the user fee structure; focused on HR and financial management improvement; enhanced use of regulatory tools and staffing for breakthrough therapy reviews; focused on communication with industry; explored RWE in regulatory decision-making

PDUFA VII (FDAUFRA, 2023-2027) | Increased staffing for cell and gene therapy reviews; incorporated allergenic extract products; introduced new pilot programs (e.g., rare diseases, real-world evidence); Enhanced product quality reviews; chemistry, manufacturing, and controls approaches; modernized IT systems



Reauthorization Process Overview

Overview of the Reauthorization Process



PDUFA reauthorization involves significant consultation with stakeholders.

PDUFA 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.

This public meeting is one of the last steps in the reauthorization process.

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Overview of Recommendations

Highlights of PDUFA VIII

- Prioritizes an America First approach to drug development, including fee incentives for companies that anchor phase 1 clinical trials in the U.S.
- Streamlines the overall agreement by ~20 pages and focuses on core review functions
- Maintains critical support for technical and scientific staff
- Advances a lifecycle approach to addressing manufacturing issues
- Enhances regulatory and financial transparency

Across the commitment letter,

- Removes one-time commitments completed under PDUFA VII
- Maintains established programs and regulatory science tools (e.g., Benefit-Risk Assessment, Digital Health Technologies)

Themes for PDUFA VIII

Pre-Market: Focuses on core review activities, enhances communication in the human drugs review program, and transitions regulatory science pilots and programs

Post-Market: Promotes safe use of medicines through continued enhancements to our drug safety system

Manufacturing: Introduces enhanced engagement, preparedness, and transparency to mitigate facility risks to regulatory approval

Finance: Enhances financial transparency and management and modifies the fee structure to incentivize clinical trials in the U.S.



Pre-Market Review: Proposed Enhancements



Mary Thanh Hai

Center for Drug Evaluation and Research, FDA

Director, Office of New Drugs

Assessment of the Program, Efficacy Supplements, and Communications

- Commits to an assessment of review processes, outcomes, and FDA-sponsor communications during first cycle review that will provide recommendations to (1) help FDA and sponsors limit complete responses for applications that are ultimately approvable, missed goal dates, and review clock extensions, and (2) increase effectiveness of FDA-sponsor communications during review

Pivotal Protocol Prioritization

- Prioritizes review of submitted pivotal protocols for studies intended to form the primary basis of an efficacy claim for a marketing application, to help ensure applicants receive feedback on critical questions prior to study initiation

Meeting Management Goals

- Highlights availability of multi-divisional meetings for sponsors developing investigational products under multiple INDs across multiple therapeutic areas to increase efficiency and alignment across participating divisions
- Adds a new process for sponsors to request that pre-IND, Type C, Type D, and INTERACT meetings be held face-to-face and for FDA to justify why a written response is sufficient, in applicable cases
- Commits to issuing a revised draft of the “Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products” guidance with information pertaining to multi-divisional meetings and written-response procedures
- Commits to an assessment of the effectiveness of the two formal meeting enhancements in PDUFA VIII: (1) requests for written responses and face-to-face meetings and (2) multi-divisional meetings to inform improvements and continuation

Expediting Drug Development and Enhancing the Use of Regulatory Science Tools

Advancing Development of Drugs for Rare Diseases

- Introduces up to 10 Rare Disease Innovation, Science, and Exploration (RISE) workshops that build on the success of the rare disease programs in CDER and CBER and address key scientific and drug development barriers
- Transitions the PDUFA VII Rare Disease Endpoint Advancement (RDEA) Pilot to a program that utilizes the established meeting framework (e.g., Type C-RDEA meeting) to discuss novel efficacy endpoint development during drug development and expands the availability of the program

Expediting Drug Development and Enhancing the Use of Regulatory Science Tools

Regulatory Science Tools to Support Drug Development and Regulatory Review

- Incorporates the Complex Innovative Design (CID) program into standard review practice where sponsors can seek advice through formal traditional meeting requests (e.g., Type C meetings)
- Expands access to the Model-Informed Drug Development (MIDD) Paired Meeting Program with a phased transition to Type C-MIDD meetings, eliminating the quarterly cadence and cap on the number of meeting requests
- Advances patient-focused drug development with the publication of case studies on how patient experience data was considered in regulatory decisions and by hosting a public meeting to discuss case studies and facilitate broader dialogue on use of patient experience data in drug development and regulatory review
- Transitions the pilot Advancing Real World Evidence (RWE) Program into practice with the review of RWE related submissions now occurring via established review practices, such as formal meeting requests

Expediting Drug Development and Enhancing the Use of Regulatory Science Tools

Communicating the Use of Regulatory Science Tools

- Commits to a public meeting to discuss best practices for communicating the use of regulatory science tools in drug development and regulatory decision-making.
- Includes publication of a summary report that may include recommendations for increasing transparency and facilitating shared learnings

Other Pre-Market Enhancements

- Sunsets the Split Real Time Application Review (STAR) Pilot Program, acknowledging limited participation during PDUFA VII
- Streamlines and consolidates the descriptions of commitments
 - Consolidates review goals into tables
 - Consolidates reviewer training
 - Combines previous sections K and L from PDUFA VII into a streamlined section on regulatory science tools
 - Moves commitments related to digital health technologies and bioinformatics support to the regulatory science section



Industry Comments



Annetta Beauregard

Biotechnology Innovation Organization

Senior Vice President, Science & Regulatory Affairs



Kristy Lupejkis

Pharmaceutical Research and Manufacturers of America

Vice President and Chief of Staff, Science and Regulatory Advocacy



Post-Market Safety: Proposed Enhancements



Amy Ramanadham

Center for Drug Evaluation and Research, FDA

Staff Director, Drug Safety Operations

Optimization of the Sentinel Initiative

- Commits FDA to maintain the high-quality and large quantity of data available to support the Agency's pharmacoepidemiology needs, advance implementation of the Sentinel 3.0 operating model through support for data infrastructure, and sustain the processes and tools required to ensure appropriate use of these data
- Streamlines annual reporting with simplified reporting of metrics describing the use of Sentinel for regulatory purposes
- Includes biannual meetings between FDA and Industry to discuss the plans for and progress of Sentinel 3.0
- Explores a potential for a process for sponsors to submit their proposed approach to a postmarket study, to enhance communication about the approach to a possible postmarketing requirement prior to product approval



Industry Comments



Ryan Kaat

Pharmaceutical Research and Manufacturers of America

Deputy Vice President, Law



Annetta Beauregard

Biotechnology Innovation Organization

Senior Vice President, Science & Regulatory Affairs



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BREAK

Check the chat for our restart time.



Chemistry, Manufacturing, and Controls: Proposed Enhancements



Sau (Larry) Lee

Center for Drug Evaluation and Research, FDA

Deputy Director, Office of Pharmaceutical Quality

CMC Facility Lifecycle Program

- Aims to decouple or mitigate the occurrence of deficiencies that, if unaddressed, may lead to multiple review cycles

CMC Facility Pre-submission Meeting

(For an NDA or BLA, Including CMC Supplements Related to Manufacturing Facilities)

- Introduces a new option for a single CMC Facility Pre-submission meeting to discuss manufacturing facilities for a proposed application submission to facilitate readiness before a facility evaluation and inspection

Post-Pre-Approval Inspection (PAI) or Post-Pre-License Inspection (PLI) Meeting

(For Original NDAs or BLAs, not Including Supplements)

- Introduces a new post inspection meeting, when needed, to discuss inspection findings that may impact application approval and corrective actions that may address identified approvability issues
- Allows FDA to extend the goal date upon receiving a meeting request package for a Post-PAI/PLI meeting when an extension would permit review of the new information provided, and there is a reasonable likelihood that review of the new information provided could address outstanding facility deficiencies relevant to the application and lead to approval in the current review cycle

CMC Facility Lifecycle Workshop and Third-Party Assessment

- Commits to publishing draft guidance describing the implementation of this CMC Facility Lifecycle Program
- Commits to an assessment and workshop focused on the implementation of the new PDUFA VIII CMC enhancements and the impact of those enhancements on facility readiness and reduction in facility deficiencies
- Sunsets the CMC Development and Readiness Pilot (CDRP) Program



Industry Comments



Annetta Beauregard

Biotechnology Innovation Organization

Senior Vice President, Science & Regulatory Affairs



Ryan Kaat

Pharmaceutical Research and Manufacturers of America

Deputy Vice President, Law



Finance: Proposed Enhancements



Josh Barton

Office of Finance, Budget, and Acquisitions, FDA

Staff Director, Resource Capacity Planning

Financial Transparency

Five-Year Financial Plan

- Continues the commitment to publish a 5-year financial plan and update the plan annually
- Updates the topics to be included in the 5-year financial plan and annual updates to focus on reporting on shared services and an index of financial- and personnel-related reporting to help external audiences navigate data provided in various reports

Annual Financial Report

- Updates the topics to be included in the annual financial report to Congress to (1) include new reporting on the operating reserve tracking, reserving, and reporting (OR TRR), and (2) enhance reporting on personnel compensation and benefits as well as operating expenses

Technical Staff Meeting

- Introduces a new technical staff meeting each year for FDA and Industry to discuss PDUFA finances and commits to publishing minutes from this meeting

Enterprise Performance Assessment

- Introduces an assessment to evaluate the operations of the PDUFA program with the goal of identifying efficiencies and whether those efficiencies should be reflected in the PDUFA revenue amounts

Proposed Statutory Changes: Revenue Framework

- Introduces a base reduction to the PDUFA program to account for the consolidation of shared services at FDA during PDUFA VII
- Sunsets the Strategic Hiring and Retention Adjustment at the end of PDUFA VII, as intended
- Modifies the capacity planning adjustment (CPA) so that it will not be applied until FDA restaffs to certain level of scientific and technical expertise and then limits the maximum increase of the CPA to 3% per year
- Reduces the operating reserve adjustment maximum balance from 14 weeks to 12 weeks
- Introduces the Operating Reserve Tracking, Reserving, and Reporting (OR TRR), which sets aside funds for restaffing and retaining scientific and technical expertise in the PDUFA program
- Updates the statute for a new Enterprise Performance Adjustment (EPA) that will allow FDA to adjust program revenue amounts to account for savings from program efficiencies, if warranted

Proposed Statutory Changes: Fee Structure

- Updates the fee structure so sponsors pay a fee equal to half the full application fee in place at the time if they anchor their phase 1 clinical trials in the U.S.
- Modifies the fee structure to charge sponsors a fee, equal to half the full application fee, for the first non-orphan supplement to an orphan-only product
- Updates the eligibility for a small business waiver to only U.S.-based companies (organized under the laws of any State)



Industry Comments



Kristy Lupejkis

Pharmaceutical Research and Manufacturers of America

Vice President and Chief of Staff, Science and Regulatory Advocacy



Steve Berman

Biotechnology Innovation Organization

Vice President, Science and Regulatory Affairs Strategy



David Spangler

Consumer Healthcare Products Association

Senior Vice President, Legal, Government Affairs & Policy



Other Topics: Proposed Enhancements



Andrew Kish

Center for Drug Evaluation and Research, FDA

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

Advancing the Development, Review, and Approval of Next Generation Cell and Gene Therapy Products

- Continues efforts to retain and strengthen staff capacity to create predictability, speed development, and meet challenges and demands of the advancing field
- Continues training, outreach, progression of novel approaches, and engagement with stakeholders to advance cell and gene therapy product development and review

Supporting Review of Allergenic Extract Products

- Notes that epicutaneous-test diagnostic products are exempt from the PDUFA program and fees beginning in PDUFA VIII, to encourage continued development of these products

Transparency in FDA Hiring and Retention of Review Staff for the Human Drug Review Program

- Continues the public webpages describing quarterly hiring updates and net CDER and CBER hires
- Commits to updates on restaffing of the PDUFA program, including prioritizing staffing for review functions and specific PDUFA VIII enhancements (e.g., Model-Informed Drug Development, Rare Diseases, Facility Lifecycle, and Sentinel)

Enhancing Transparency and Leveraging Modern Technology

- Continues quarterly meetings between FDA and regulated industry to provide updates and collaborate on IT initiatives, challenges, and emerging needs relevant to PDUFA
- Commits to engaging regulated industry in pilot testing of enterprise-wide systems
- Maintains the data standards catalog and regular updates to the catalog
- Continues engagement with stakeholders and international consortia to promote convergence and adoption of international standards, as appropriate

Note: Previous sections related to Bioinformatics Support and Digital Health Technologies were moved to Section I.L, “Expediting Drug Development and Enhancing the Use of Regulatory Science Tools”.



Industry Comments



Steve Berman

Biotechnology Innovation Organization

Vice President, Science and Regulatory Affairs Strategy



Kristy Lupejkis

Pharmaceutical Research and Manufacturers of America

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Public Stakeholder Perspectives



Steve Wosahla

Children's Cancer Cause



Marc Yale

International Pemphigus and Pemphigoid Foundation



Tingting Zhang

Hear2Care



Megan Miller

Critical Path Institute



Reshma Ramachandran

Yale Collaboration for Regulatory Rigor, Integrity, and Transparency



Thomas Hwang

Brigham and Women's Hospital; Harvard Medical School



Kara Berasi

Haystack Project



Diana Zuckerman

National Center for Health Research



Jon McCord

Physicians Committee for Responsible Medicine



Jeff Allen

Friends of Cancer Research



Tim Scott

Biocom



Suzanne Robotti

MedShadow Foundation



Jamie Sullivan

The RARE Foundation



Andrew Coats

On behalf of Bruce Carroll for Telix Pharmaceuticals (U.S.)



Ryan Fischer

Foundation for Angelman Syndrome Therapeutics



Mary Hilley

Humane World for Animals



Patricia Kelmar

U.S. PIRG



Taylor Livelli

1Day Sooner



Alexander Naum

Generation Patient



Erin O'Quinn

Parkinson's Foundation



Michael Abrams

Public Citizen



Kathryn Lowell

NORD



Public Comment



Closing Remarks

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