PRIA Coalition Quarterly Stakeholder Meeting

Steve Schaible, OPP PRIA Coordinator

U.S. Environmental Protection Agency

Office of Chemical Safety and Pollution Prevention

Office of Pesticide Programs

August 16, 2023

AGENDA

- Welcoming Remarks/Ground Rules
- OPP Organizational Chart and Hiring Update
- Front End Processing Update
- IT Update
- Gold Seal Letters Update
- Update for PRN 98-5
- FY'23 Fees Collected Through 8/4/23
- FY'23 PRIA Metrics to Date
- FY'23 (to date) Non-PRIA Fast Metrics/Division Updates
- PRIA 5 Implementation Activities
- Registration Review Update
- Wrap-Up/Next Meeting Dates

Office of Pesticide Programs

Edward Messina, Director
Leo Gueriguian, Deputy Director, Management
Michael Goodis, Deputy Director, Programs
Monique Perron, Senior Science Advisor

Endocrine Disruptor Screening Program
Catherine Aubee,
(Acting) Senior Advisor

Antimicrobials Division
Anita Pease, Director
Kristen Willis, Deputy Director
Elizabeth Donovan, (Acting) Assc. Director

Biopesticides and Pollution Prevention Division
Madison Le, Director
Frank Ellis, (Acting) Deputy Director

Registration Division
Charles "Billy" Smith, Director
Daniel Rosenblatt, Deputy Director
Jennifer Saunders, (Acting) Assoc. Director

Pesticide Re-evaluation Division
Elissa Reaves, Director
Tim Kiely, Deputy Director

Health Effects Division
Dana Vogel, Director
Donald Wilbur, Deputy Director
Greg Akerman, Associate Director

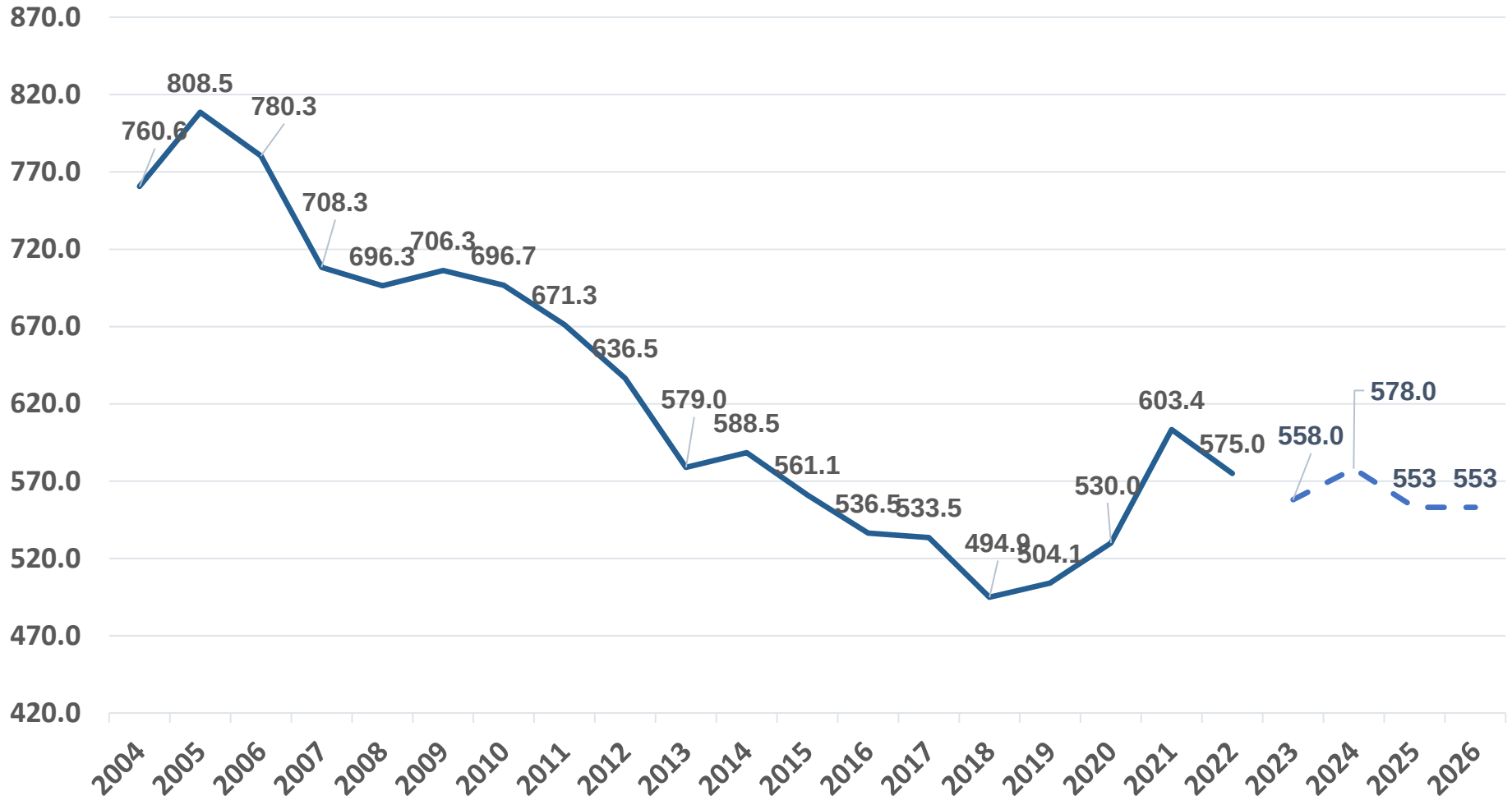
Environmental Fate and Effects Division
Jan Matuszko, Director
Amy Blankenship, (Acting) Deputy Dir.
Brian Anderson, Assoc. Director

Biological and Economic Analysis Division
Anne Overstreet, Director
Neil Anderson, Deputy Director

Hiring Update

- Status of new hiring activity
  - EPA has hired 20 new people this fiscal year, with 15 additional hires expected by the end of the fiscal year;
  - EPA has experienced a loss of 43 people to date this fiscal year;
    - The typical attrition rate is around 4.7%; to date in FY23 OPP is experiencing an attrition rate of around 8%.

EOY Total FTE Usage for OPP from FY 2004 - FY 2026



95 FTE deducted from the OCSPP Program funding levels to normalize the data to reflect OCSPP Reorganization and those FTE being moved to OPS.

Front End Processing Delays

- EPA has encountered several issues related to front-end processing over the past year
  - October 2022-February 2023, PRIA actions were delayed during the front-end process due to both resources and IT challenges
  - June 2023, issues with E-Studies module delayed contractor completions of the 21-day screen
  - July 2023 (7/13-7/27), EPA's E-Submission module was down which prevented EPA from processing incoming actions
- Short-term fixes: focus on process and communication
- Longer-term fixes: integration and automation

EPA IT Update

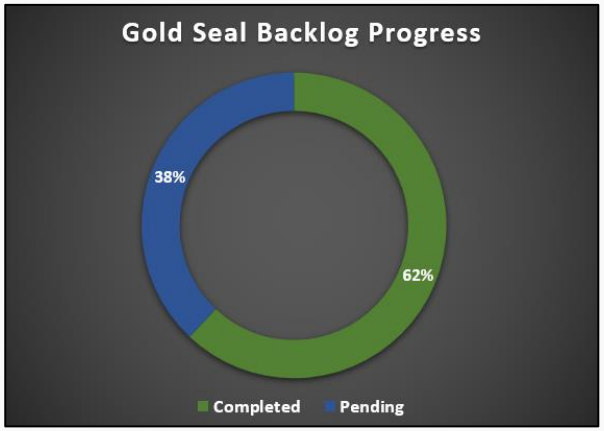
- The Mission Support contract for EPA's IT modernization is ongoing
  - OPP management team holds weekly meetings with contractor to discuss progress and plans
- Expect to migrate all of OPP to Salesforce by end of FY23
  - Conventional registration
  - Registration Review for PRD, AD and BEAD
  - DCI generation module
- Working to fulfill other PRIA 5 IT requirements, including external viewer
- OPP also developing an IT Feasibility and Priorities document
  - Focus on intermediate-term plan for IT development over the next several years

EPA IT Update Cont.

- The eCSF builder pilot is open and able to accept formulation statements as standardized PDFs (38 received to date)
  - EPA working on some outreach to see how adoption of eCSF could be promoted/expanded
  - Potential for further development of tool?
- Currently building an international coalition of fellow regulators for digital label harmonization
- Working with industry and fellow regulatory agencies to develop a phased developed plan for a fully digitized label
  - PPDC Label Workgroup
- Drafting a White Paper on the Benefits of Adopting a Structured Digital Label

Gold Seal Status Update

- A workaround for the front-end issues was created and the Agency stared working on the backlog in late June.
- At this time **62%** of the backlog has been completed.
- Due to the volume of actions and parallel process occuring, the Gold Seal team cannot provide a timeline on when specific Gold Seal requests will be completed at this time.
- In the fall, the Agency will begin piloting a process allowing all regulatory divisions to manage and process their own Gold Seal letters.
- Registrants are encouraged to send a list with the EPA Registration Numbers of their submitted actions to goldsealletters@epa.gov or Shanta Adeeb at adeeb.shanta@epa.gov.



EPA is Updating Current PR Notice 98-5

- For EPA Form 8570-35, Data Matrix, two different copies of the form were created by the notice, a “Public File Copy” and the “Agency Internal Use Copy”.
  - EPA has released the Agency Internal Use Copy under FOIA, after a product is registered.
  - The public file copy does not contain the guideline reference number, the guideline study name, and the MRID number; however, none of this information is CBI and it is released under FOIA
  - EPA will be asking for only one form to be submitted.
- An FR notice will announce the revised form and request comment

FY’23 Fees Collected as of 8/11/23

PRIA Fees: $18.3M

Maintenance Fees: $39.9M

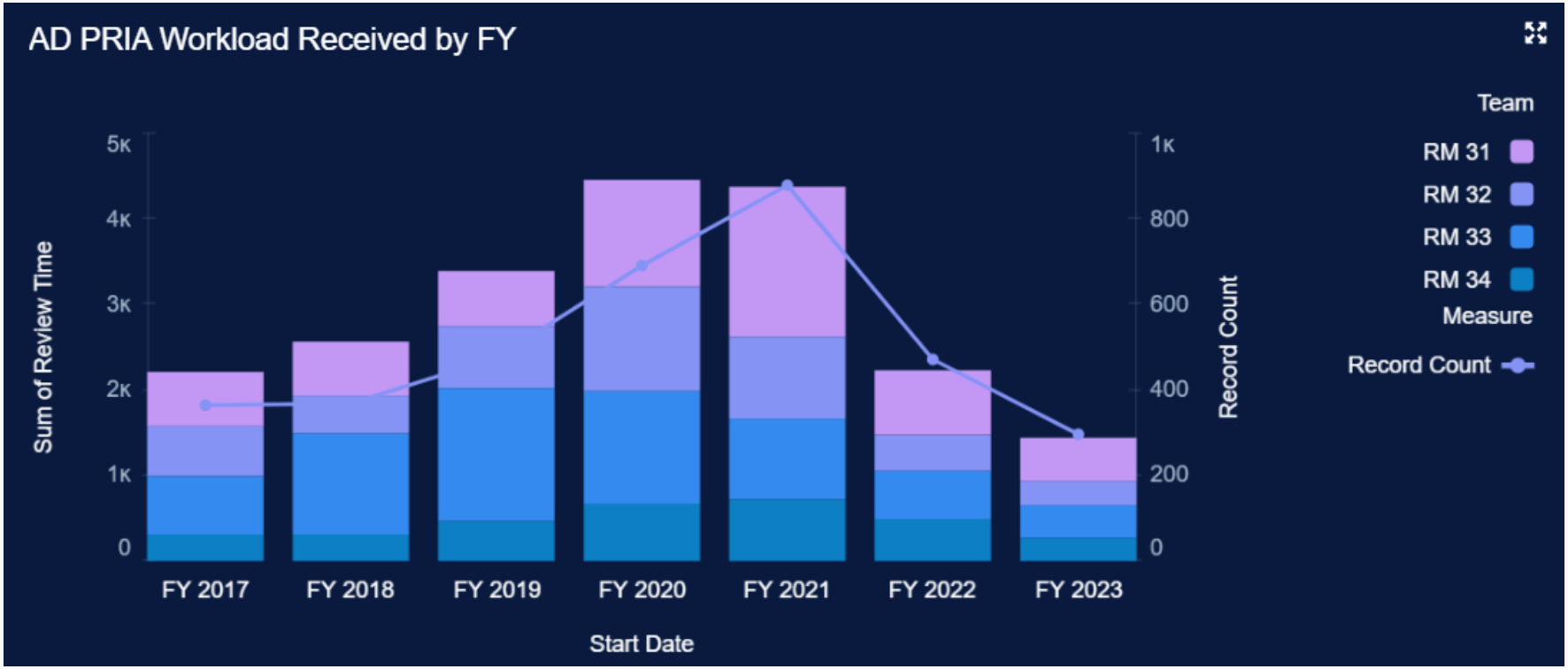
PRIA 5 Renegotiation Update

- EPA has not functionally renegotiated since the May/June timeframe (depending on division)
  - Providing "projected completion dates" via email when possible
    - Some situations are challenging to do this
    - Green, Yellow, Red tracking
      - Green: have all that is needed to complete action, date should be provided
      - Yellow: waiting on something to move action forward (*e.g.*, waiting on data submission), date could potentially be provided on a case-by-case basis
      - Red: action likely can't move forward at this time, communicate a date can't be provided at this time (*e.g.*, ESA issues, litigation issues)
  - Working on internal guidance to make this communication more consistent
- Development of a renegotiation decision tree

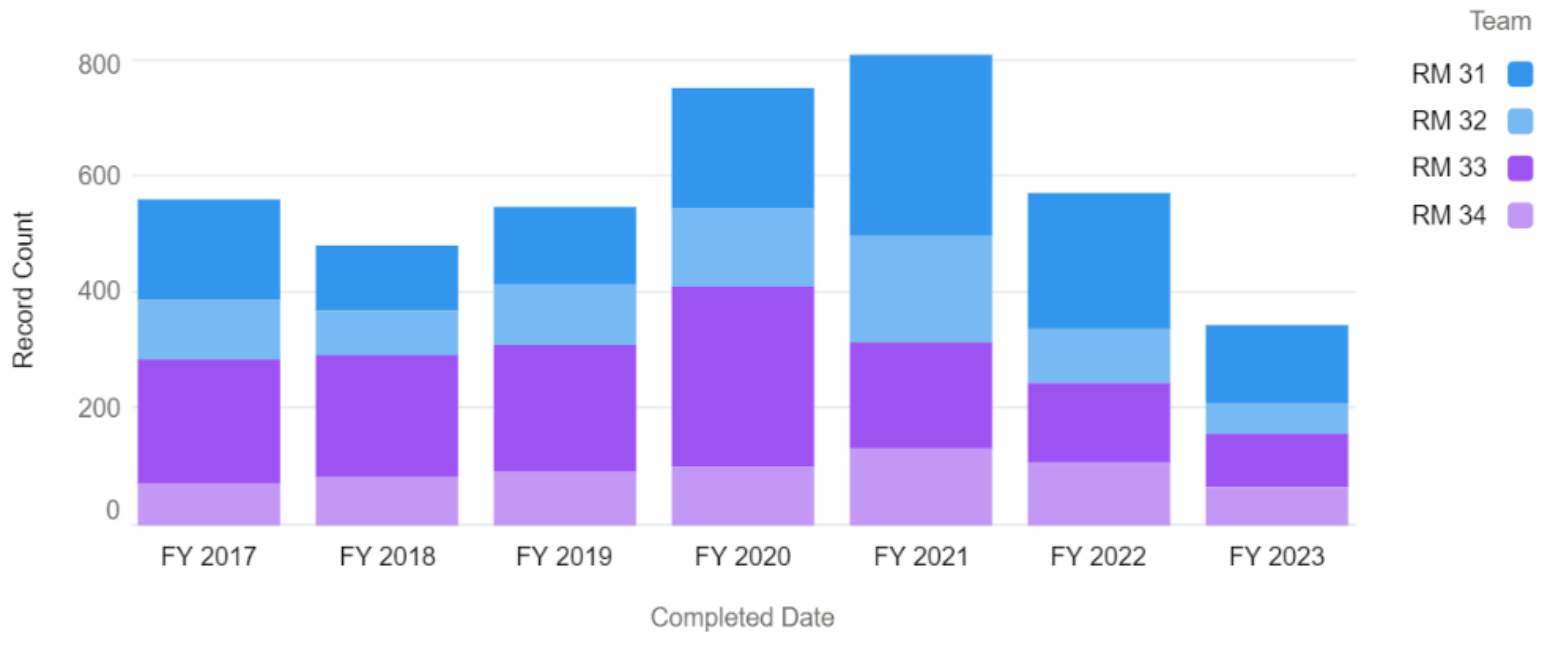
Future Metrics Reporting

- Reporting requirements from PRIA 5
  - Dates of any renegotiations and dates to which action is renegotiated
  - Tracking reason(s) driving renegotiations
- Tracking reasons driving late PRIAs
- Overall decision review timeframe to complete action by PRIA category and activity
  - Degree to which original timeframe is exceeded
- What other future metrics are desired?

AD PRIA Received FY17-FY23 (as of 8/14/23)



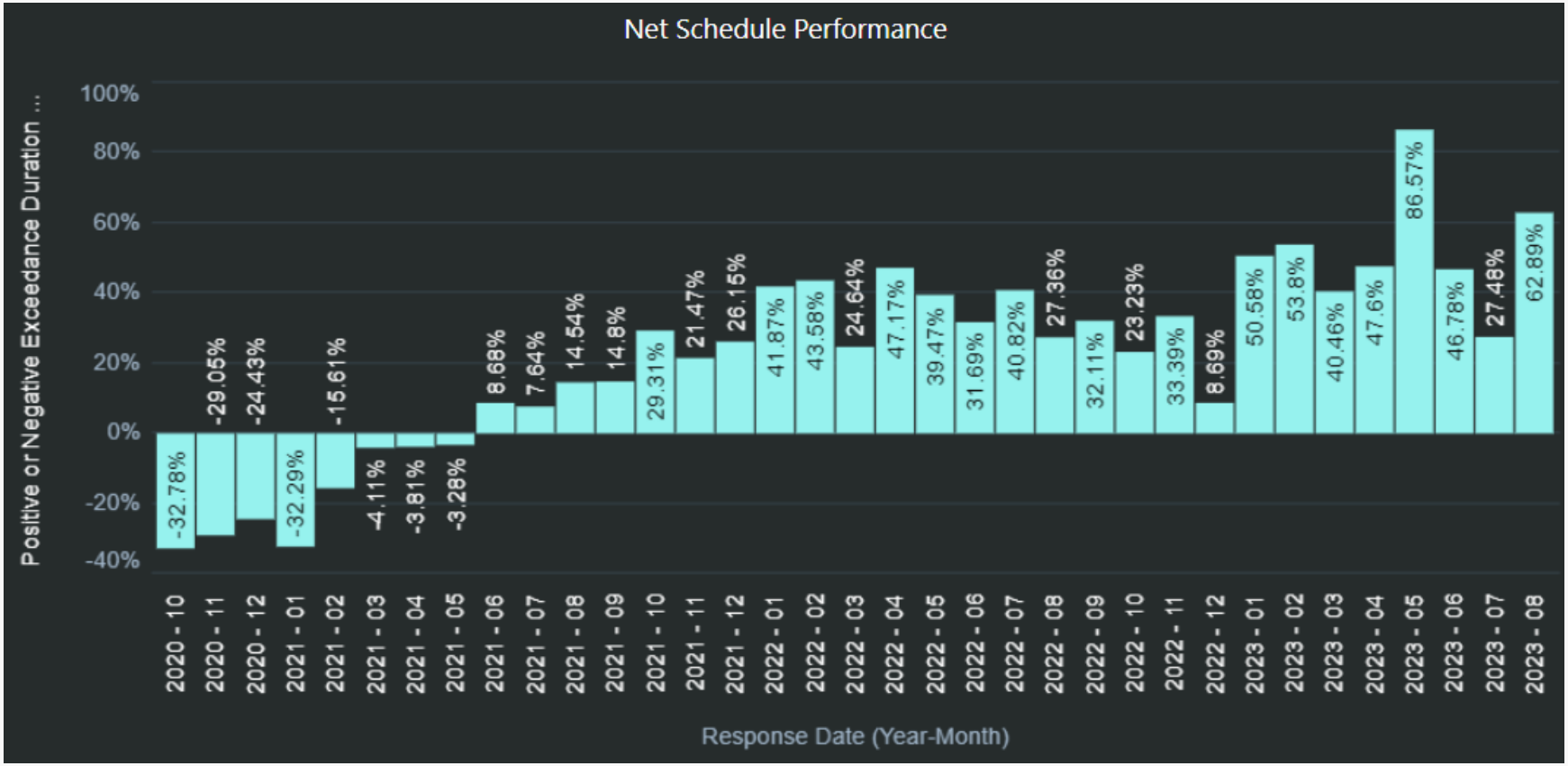
AD PRIA Completed FY17-FY23 (as of 8/14/23)



AD Net Schedule Performance FY23 (as of 8/14/23)

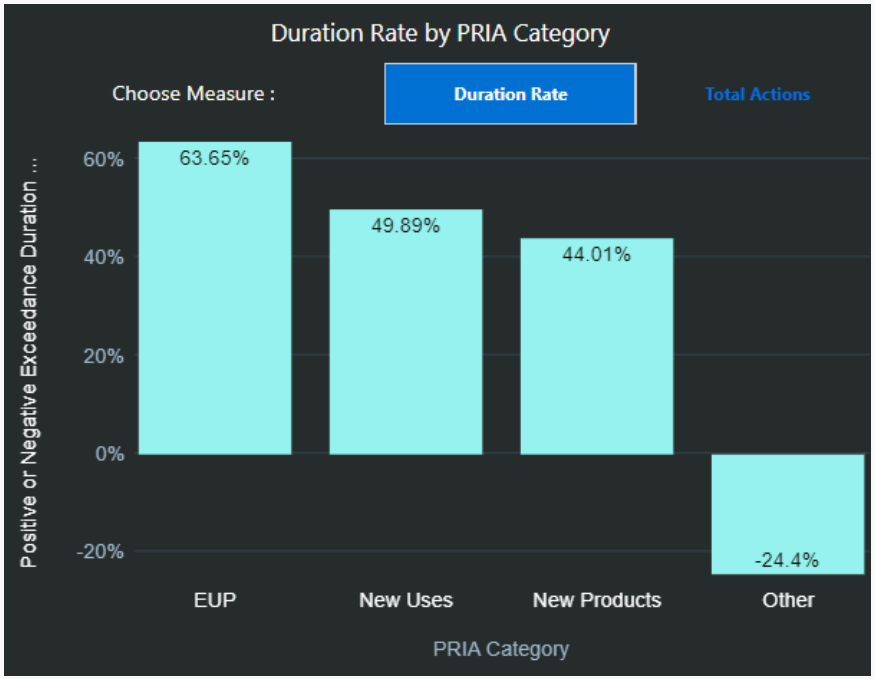
*Represents completion of PRIA actions relative to original PRIA date.

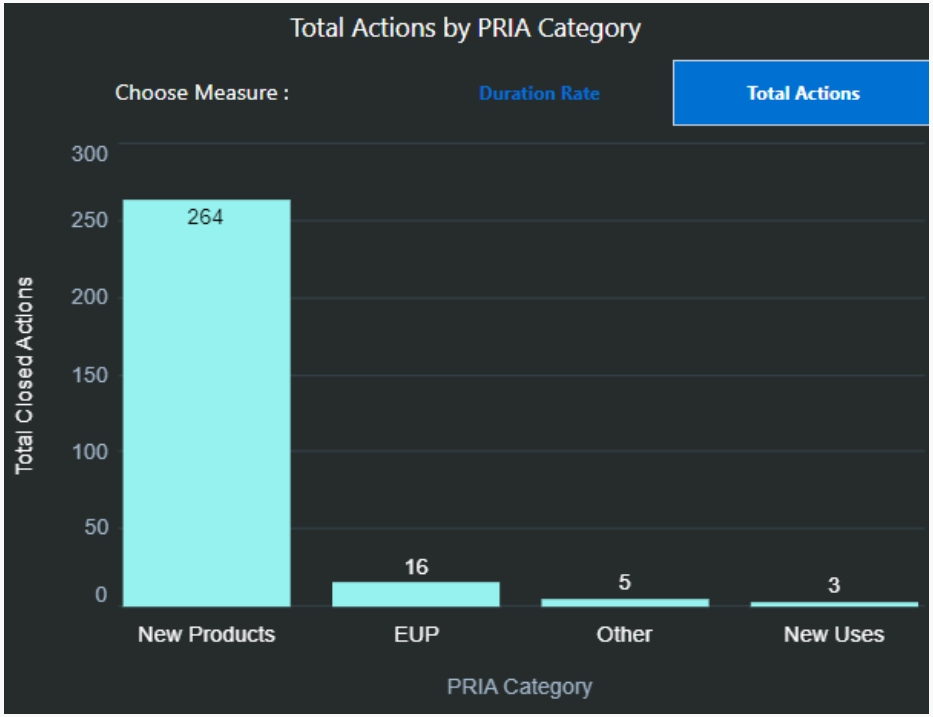
AD Net Schedule Performance FY21-FY23 (as of 8/14/23)



*Represents percent of time original PRIA dates were exceeded across all actions per month.

AD Net Schedule Performance FY23 (as of 8/14/23)



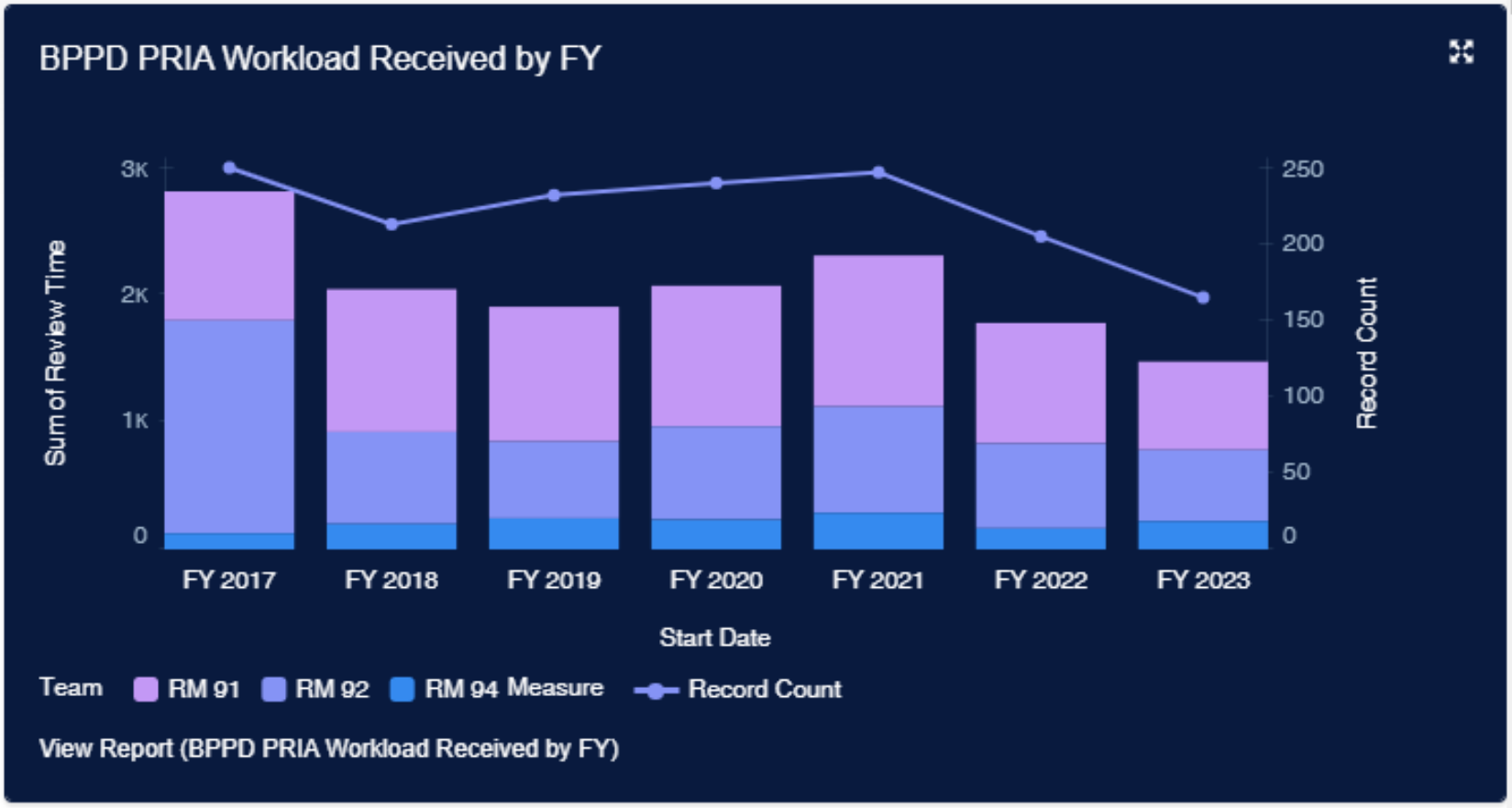


*Represents percent of time original PRIA dates were exceeded and total completed actions during that time period.

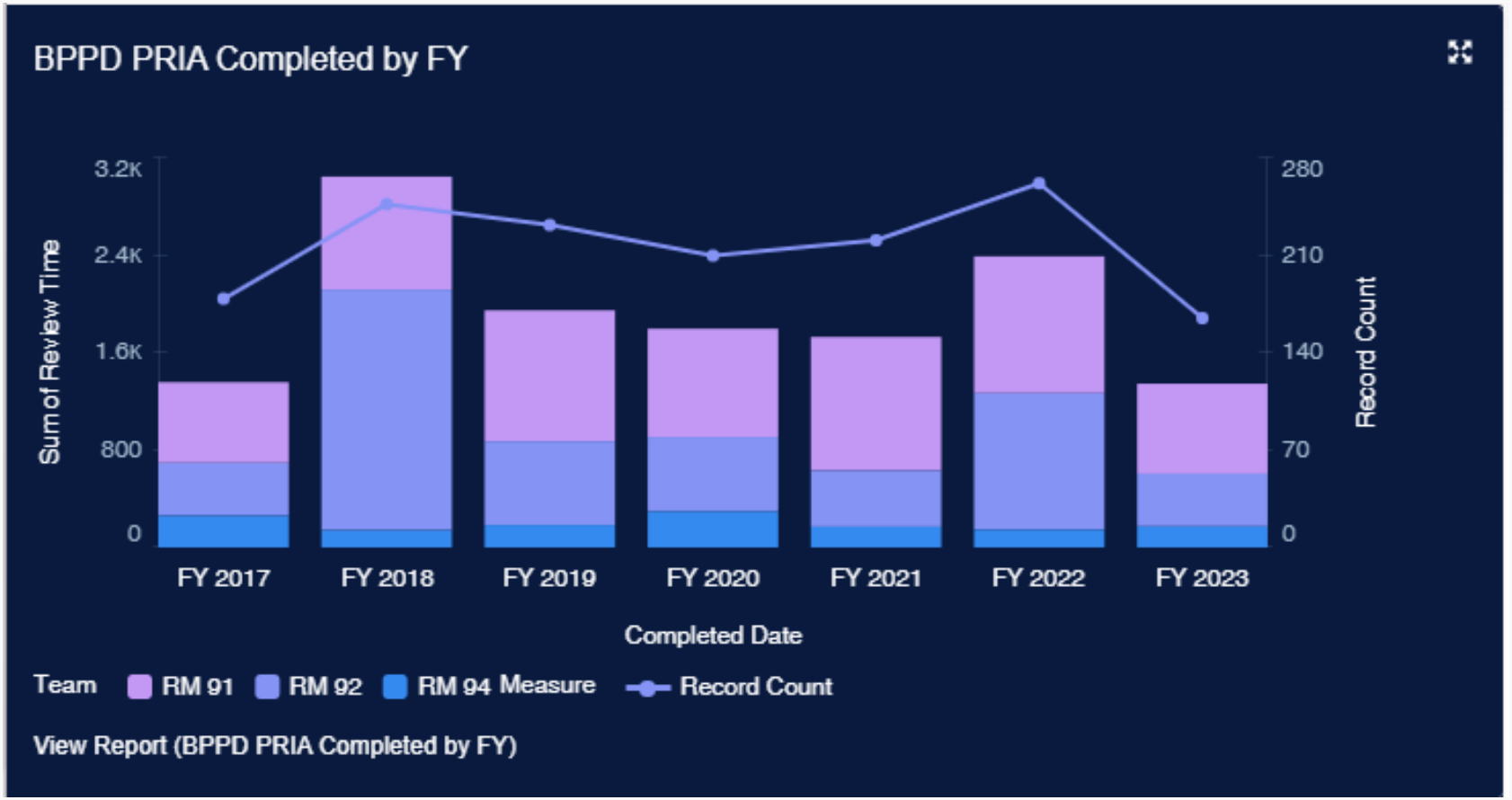
AD Late PRIA Tracking and Completion

- AD is currently tracking 72 late PRIAs
  - 80% of those are late due to agency delays
  - 20% due to registrant delays
- Of those late due to agency delays the major reasons are split between
  - Efficacy (29%)
  - Product chemistry (22%)
  - Regulatory (19%)
  - Risk assessment (19%)
  - The days late range from 4 days to 141 days late and counting.
- To date we have completed 17 PRIAs late
  - Average 65 days late
  - Range of 9-112 days late

BPPD PRIA Received FY2017-FY2023



BPPD PRIA Completed FY2017-FY2023

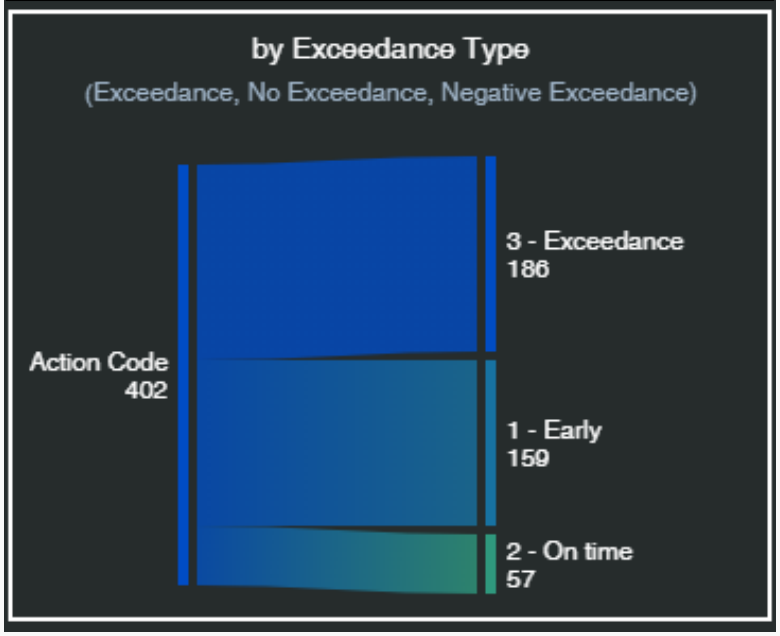


Summary of BPPD PRIA Actions Completed in FY2023 (as of 08/15/2023)

Total PRIA Applications Commpleted	**166**
New Active Ingredients (AI)	**27**
New AI product	19
New AI Tolerance Petitions	8
New Uses	**11**
New use products	5
New use amendments	4
New use tolerances petitions	2
Experimental Use Permits (EUPs)	**8**
New permit and amendments	6
Experiment use permit tolerance petitions	2
New Products	**52**
Amendments	**33**
Other Actions (e.g., Preapplications, misc actions, biotech notifications)	**34**
Inert PIP Tolerance Petition	**1**
PRIA withdrawn (out of 166 total PRIA actions)	25
PRIA rejected as a result of preliminary technical screening (out of 166 total PRIA actions)	5

BPPD Net Schedule Performance

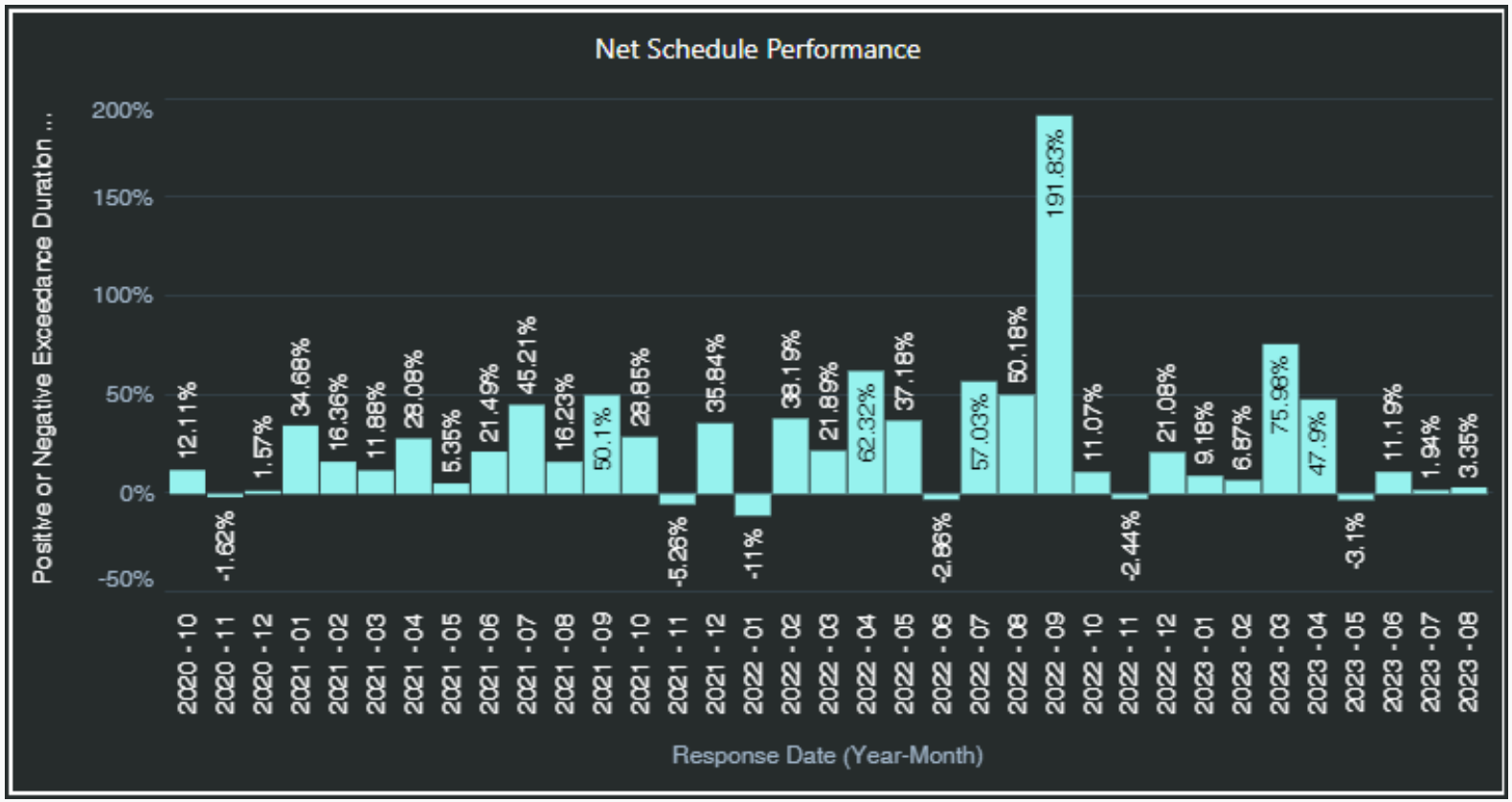
FY21-FY23



FY23

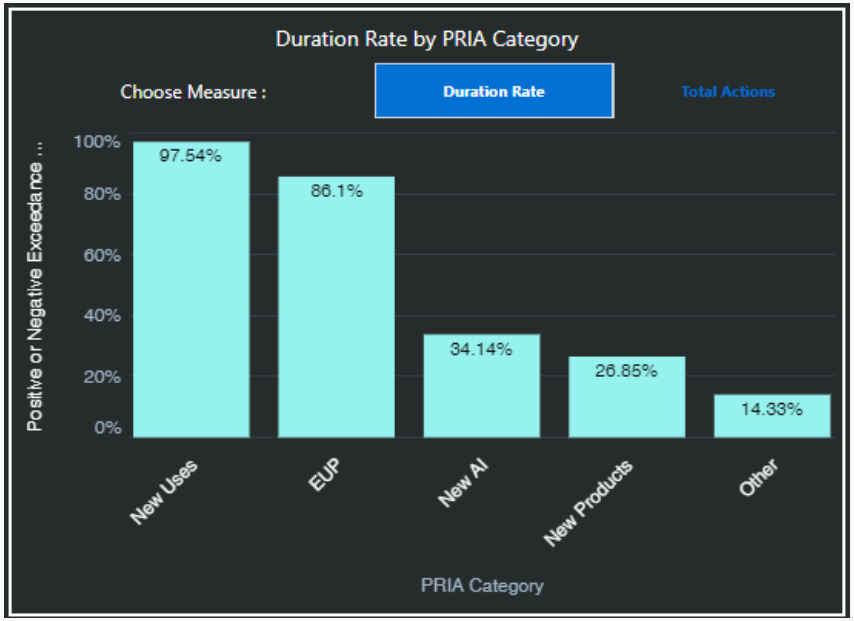
*Represents completion of PRIA actions relative to original PRIA date.

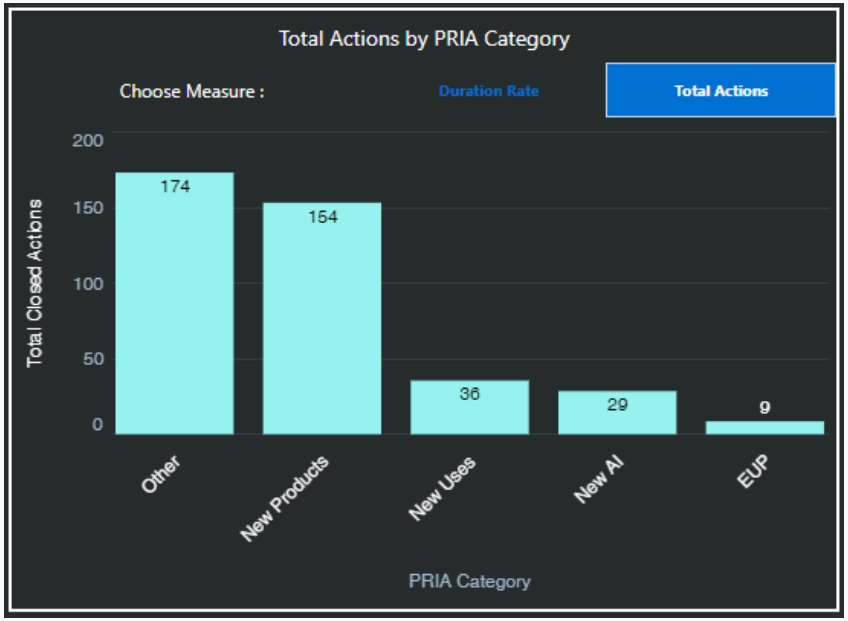
BPPD Net Schedule Performance FY2021-FY2023



*Represents percent of time original PRIA due dates were exceeded across all actions per month.

BPPD Net Schedule Performance FY2021-FY2023





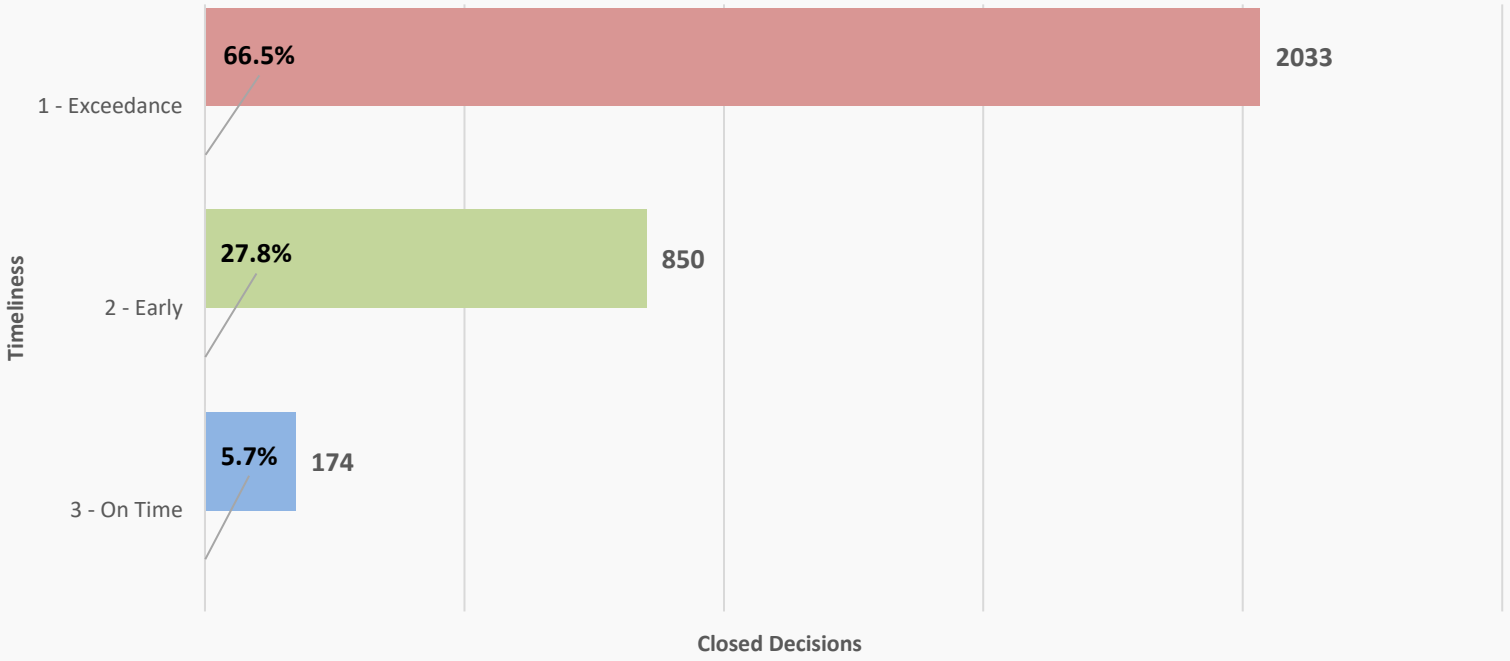
*Represents percent of time original PRIA dates were exceeded and total completed actions during that time period.

BPPD Late PRIA Tracking and Completion (as of 08/15/2023)

- BPPD is currently tracking 42 late PRIAs
  - 71% due to Agency delays / Days late range from 1 – 118 days
  - 29% due to registrant delays / Days late range from 1 – 230 days
- Of those late due to Agency delays (30), the major reasons are split between
  - Human health toxicology (~43%)
  - Endangered Species Act assessment (~30%)
  - Regulatory (~13%)
  - Ecological toxicology, front end, Office of General Counsel, and product chemistry (each ~3%)
- To date, BPPD has completed 4 late PRIAs
  - Average: 49 days late
  - Range: 7 – 85 days late

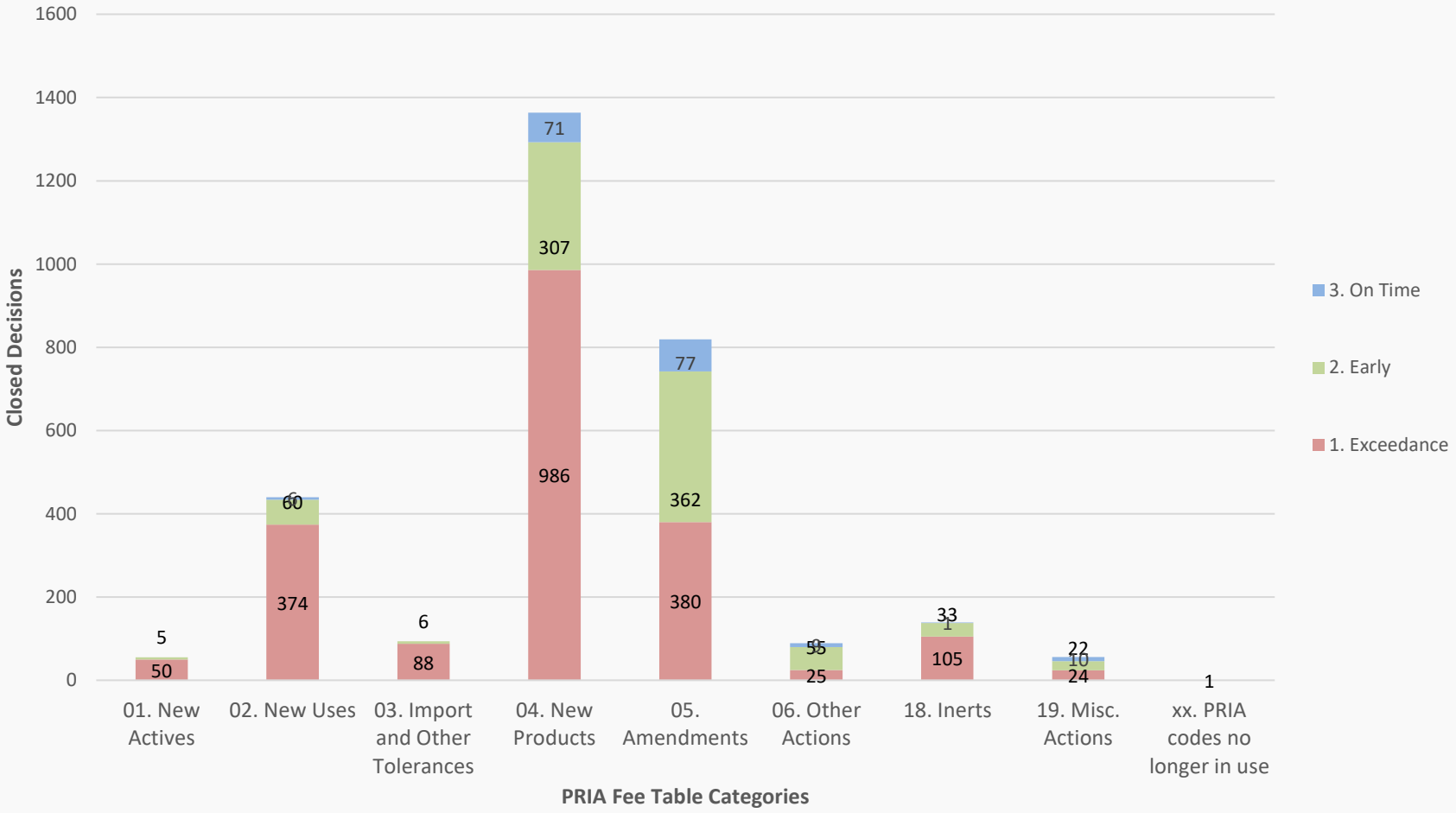
RD On-Time Performance for FY21-FY23 Closed Decisions

Includes I , R and M Codes except Gold Seals, Excludes Label Reviews
- Based on Original PRIA Due Date -



RD On-Time Performance for FY21-FY23 Closed Decisions

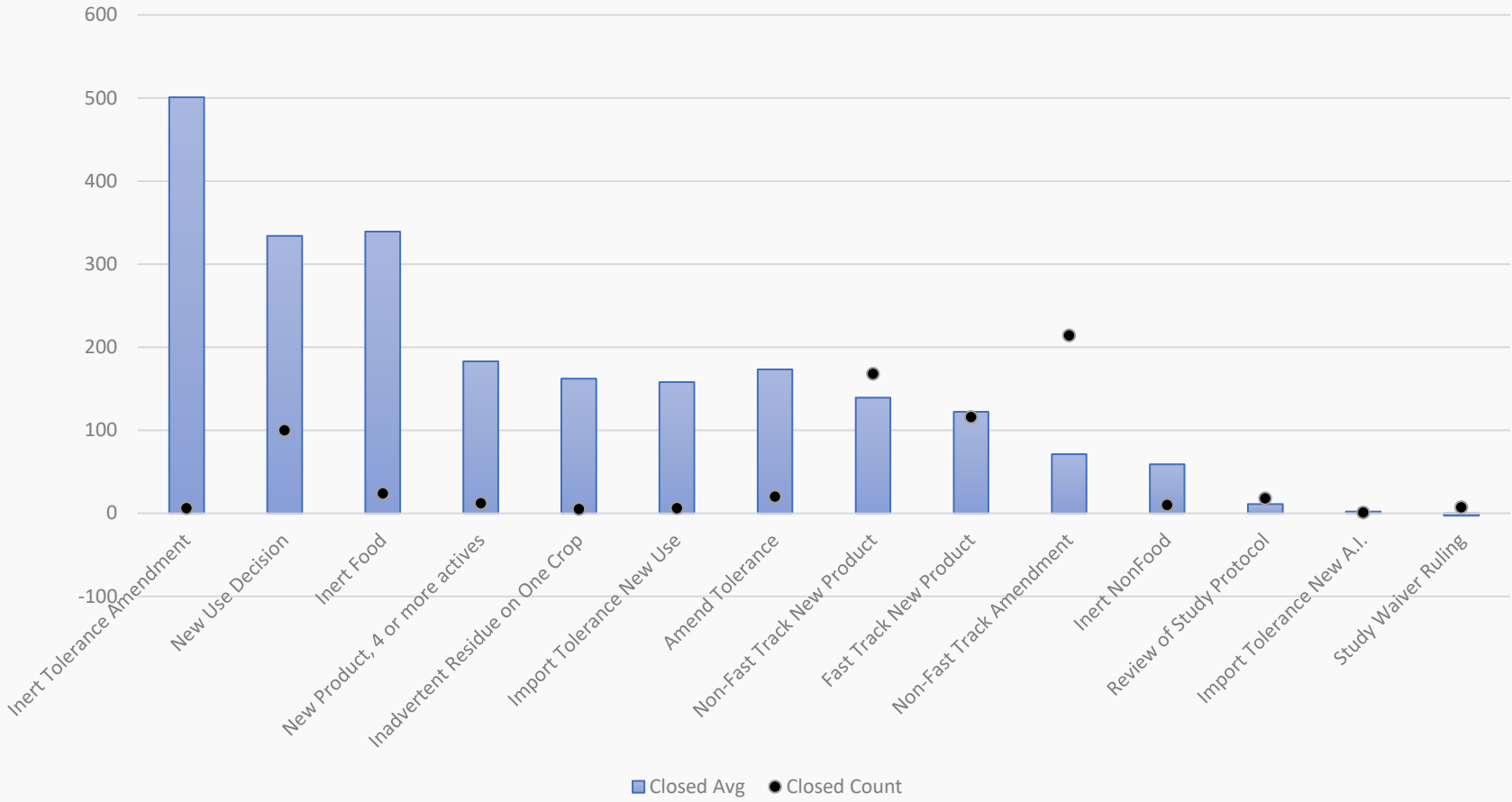
by PRIA Fee Table Categories



High Level RD FY23 PRIA Update (as of 8/14/23)

- RD has closed 715 PRIA actions
  - Includes ~100 New Use Actions, ~300 New Product Actions, ~235 Amendments, and ~40 Inert Actions
  - Only 1 new active ingredient but plan to complete 2 more
- RD has had an additional 106 actions withdrawn
  - Includes ~70 New Product Actions and ~20 Amendments
- RD has 30 “Not Grants”
  - 2 New Use Actions, 26 New Product Actions, and 2 Amendments
  - For reference, RD had 35 “Not Grants” in FY22

RD Average Days Past PRIA Date for FY23 Completions (as of 8/14/23)



Antimicrobials Division- Notification Closeout

- On June 29th, 2023 AD closed out all notifications submitted before 10/1/2022:
  - This included ABN, CSF and label notifications
  - Resulted in ~ 2,000 notifications being closed
  - Upon request, AD will create a company specific report of the actions closed out.
    - Reach out to the appropriate PM for a list.
  - The closed notifications were not given Agency letters and labels were not entered in PPLS.
  - The states were informed of the close out plan and a list of closed out submissions was provided.
- This followed the close out of notifications and other non-PRIA actions (e.g., fast-track, 6(a)2) for cancelled products(~1000) that were closed out in Q2.

Antimicrobials Division- Non-PRIA Amendment Consolidation and Prioritization Initiative

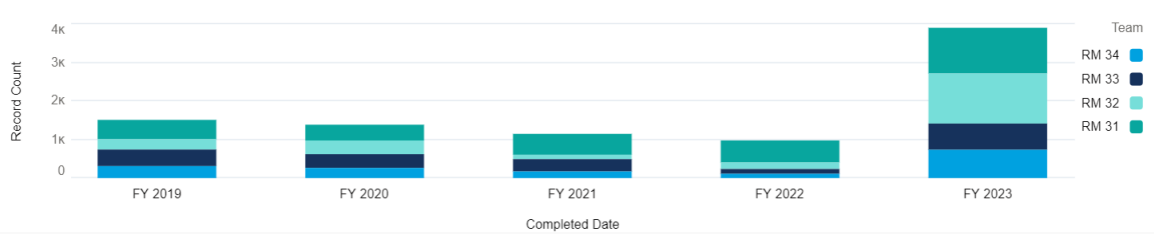
- There are currently ~4,000 non-PRIA amendments in backlog status.
  - This includes fast-track amendments (including minor formulation amendments and non-PRIA label amendments)
- In the coming weeks, AD will be contacting registrants with a company specific list of amendment actions submitted to EPA.
  - Companies will be asked to:
    - indicate amendments that can be voluntarily withdrawn.
    - provide a top 10 priority (or less) list and indicate if actions can be bundled with other non-PRIA actions.

AD Salesforce Non-PRIA Completions (as of 8/14/23)

FY23

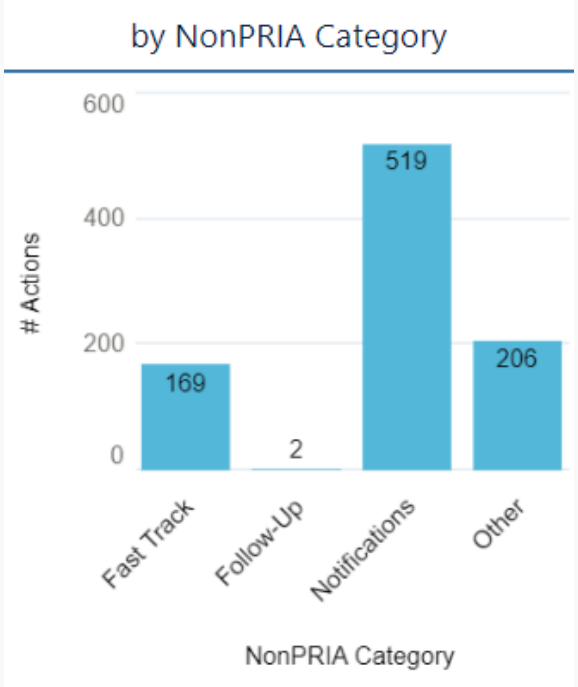
Note: ~75% of the FY23 completions are due the notification closeout and closeout of actions associated with cancelled products

Completed FY19-FY23

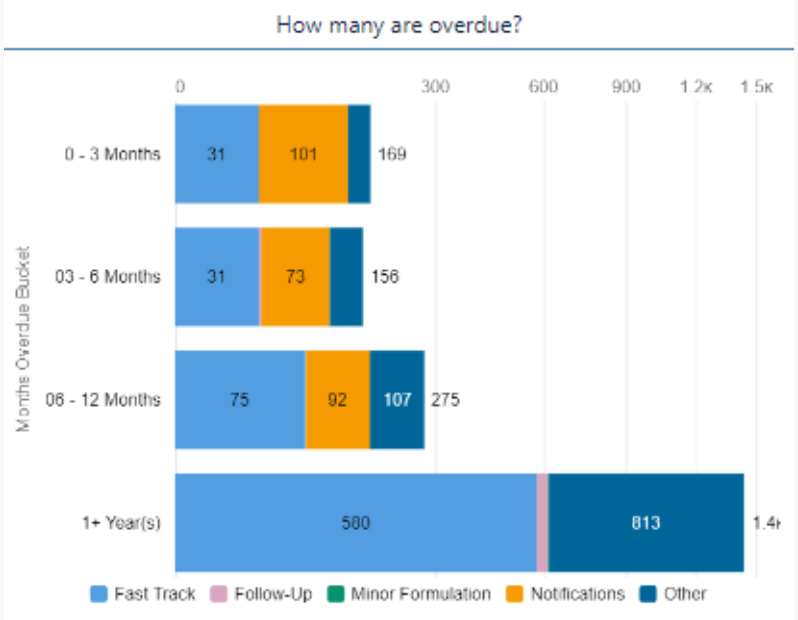


AD Salesforce Non-PRIAs (as of 8/14/23)

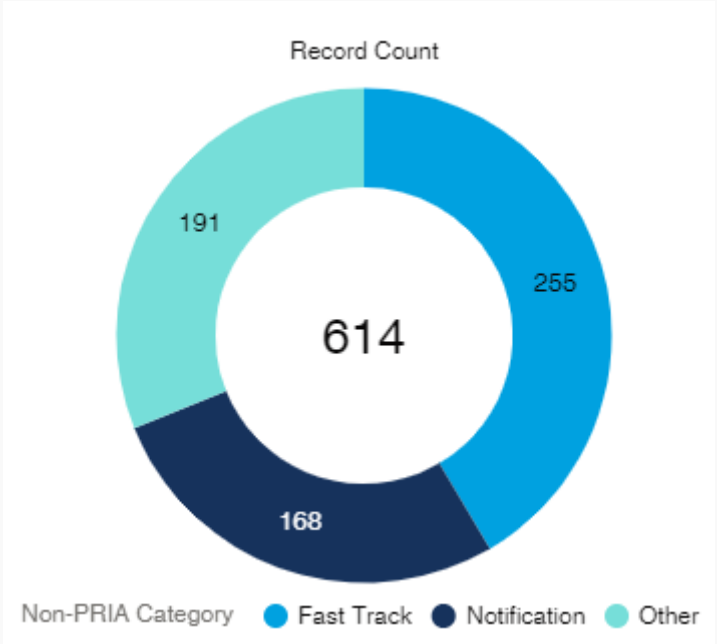
Actions received FY23



Overdue actions FY18-FY23



BPPD Salesforce Non-PRIA FY2023 Completions (as of 08/15/2023)

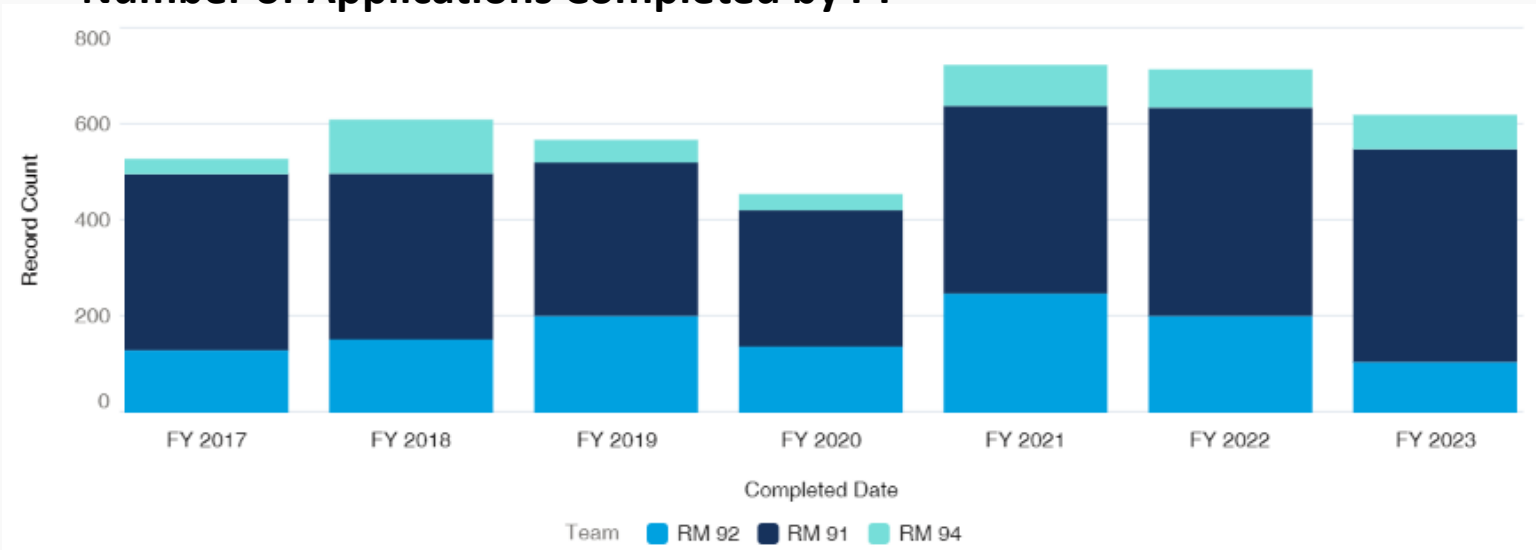


- BPPD has completed 614 non-PRIAs
  - 255 Fast-track Amendments
  - 168 Notifications
  - 191 Others (e.g., responses to terms or conditions of registration, incident reports, etc.)

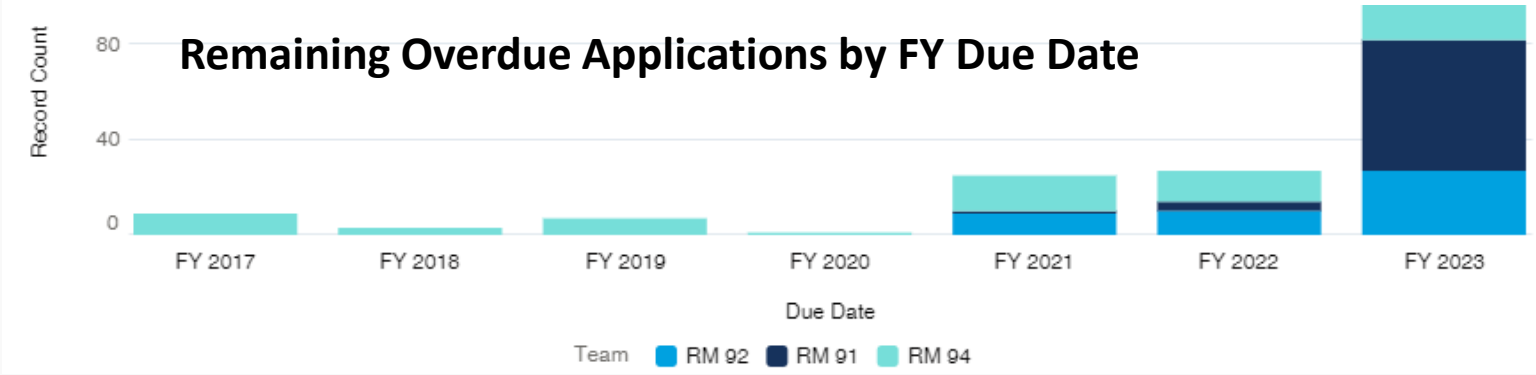
BPPD Salesforce Non-PRIA FY2017-FY2023

(as of 08/15/2023)

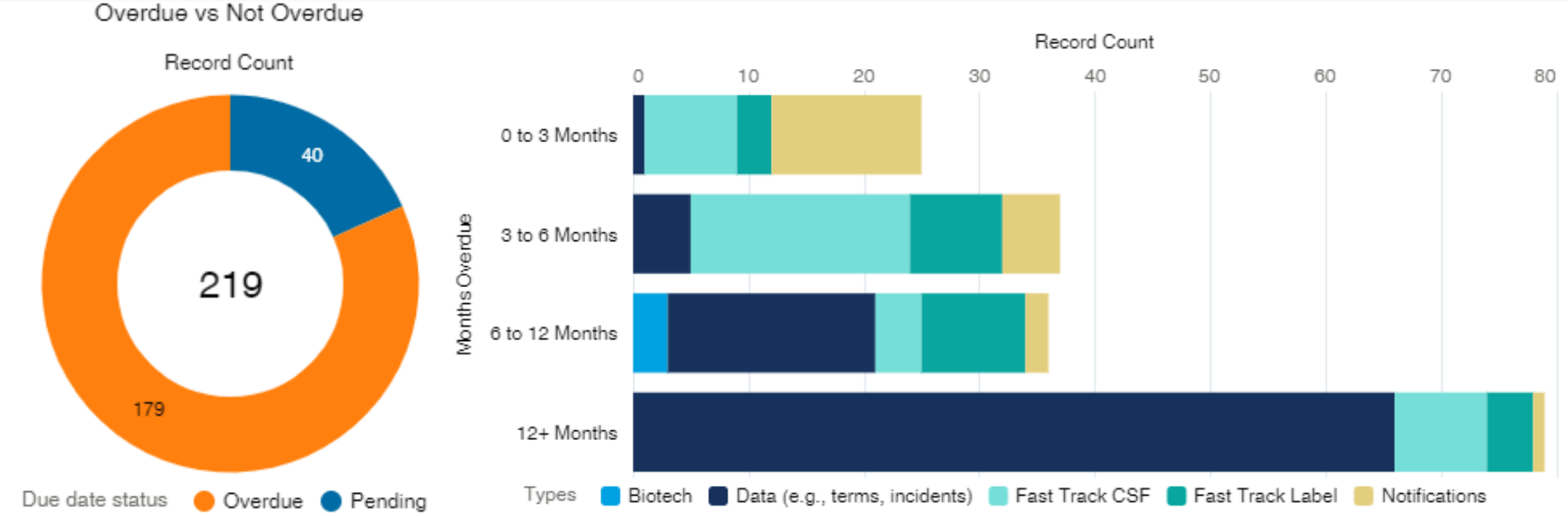
Number of Applications Completed by FY



Remaining Overdue Applications by FY Due Date



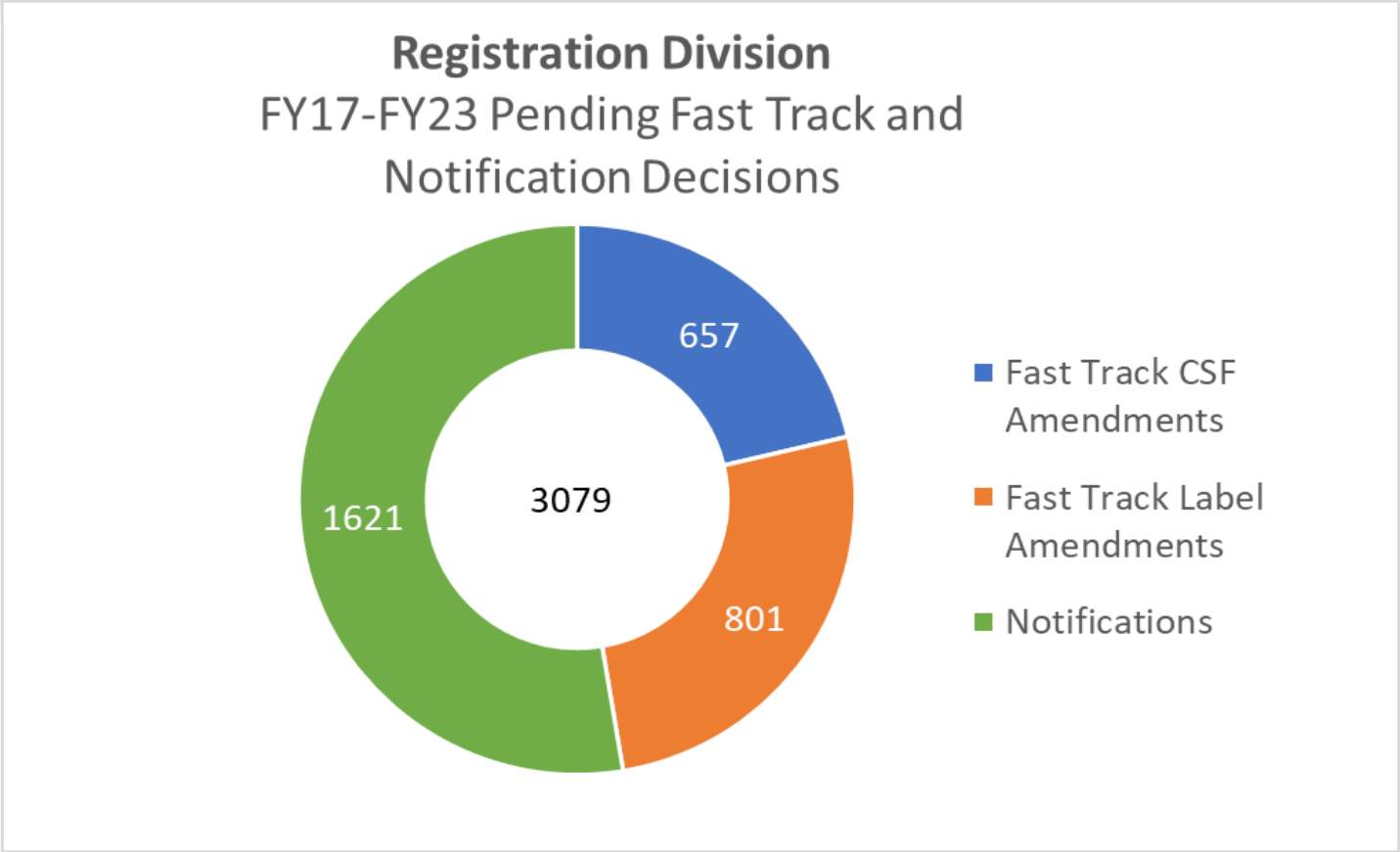
BPPD Salesforce Non-PRIA "Backlog" FY2017-FY2023 (as of 08/15/2023)



RD Non-PRIA FY23 Completions (as of 8/10/23)

RD has completed:

- **528** Fast Track Label and CSF Amendments
- **1070** Notifications (labels and CSFs)
  - Includes ~200 hundred rejected notifications, RD working on notification rejection reasons report
- **66** Minor Formulation Amendments
- **21** Section 18s (excluding 10 withdrawn and 1 amendment)
- **226** SLNs (includes all SLNs in house over 90 days)



- Chart above excludes “hanging receipts” awaiting assignment of decision # and action code.

RD Non-PRIA Submissions and Initiatives

- Renewed focus on notification and fast track amendment actions
- Creating a strategy to reduce the backlog and streamline for the future
- Actions we intend to take in the coming months include:
  - meeting with major registrant groups to discuss efficiencies/areas of concern and how to potentially reduce submissions
  - contacting the top non-PRIA submitters with a list of their pending non-PRIAs to identify any potential actions that can be withdrawn
  - sharing lists of common reasons for notification rejections and common issues for fast-track submissions to increase submission quality
  - scheduling division-wide focus days for notifications and fast tracks
- Currently considering whether to implement a strategy similar to AD's (close out old notifications without review and ask for fast-track priorities)
  - RD's upcoming move to Salesforce would help facilitate any of these type of efforts

PRIA 5 Implementation- FY 2023 Due Dates

- **June**:
  - Seek stakeholder input on ways to make bi-lingual labeling accessible to farmworkers;
  - Post to a single webpage guidance related to risk assessment, risk mitigation, benefits, assessment, and cost-benefit balancing, as well as hyperlinks to resources (e.g., pesticides exempt from registration under section 25(b)
- **September**:
  - Issue ESA guidance to registrants for outdoor uses of new active ingredients, registration review cases
- **December**:
  - Establish VERV program
  - Issue ESA guidance to registrants for new outdoor uses of registered active ingredients
  - Establish grant program to develop training curricula
  - IT Update deliverables
  - Issue process assessment contract
- EPA webpage on PRIA 5 Implementation: https://www.epa.gov/pria-fees/pria-5-implementation

Pesticide Registration Review

- In 2007, an amendment to FIFRA formalized a requirement that EPA review each registered pesticide at least every fifteen years – this is what we call registration review.
- The FY2023 Omnibus Bill provided a four-year extension for the registration review deadline for the pesticides registered before October 1, 2007.
- The deadline for the completion of registration review final decisions is now October 1, 2026.
- The Bill requires interim decisions (IDs) to include "measures to reduce the effect of the [pesticide]" on listed species and designated critical habitats if EPA has not "made effects determinations or completed any necessary consultation under [ESA Section 7(a)(2)]."
- EPA affirms its aggressive plan to review all remaining pesticide cases and issue decisions to protect humans, endangered species, and the environment, while providing pesticide users with predictability about the legal status of pesticides in registration review.
- New Pesticide Registration Review Schedule located here: https://www.epa.gov/pesticide-reevaluation/upcoming-registration-review-actions

Pesticide Registration Review Progress

- There are 789 cases with a registration review deadline before October 1, 2026. EPA has:
  - Completed 715 draft risk assessments (91% of total number of cases), evaluating the potential for human health and ecological effects of a pesticide
  - Completed 678 proposed interim or proposed final decisions (86% of total number of cases)
    - which present EPA's responses to public comment on draft risk assessments and which propose label mitigations and/or restrictions so that a pesticide product can continue to be used safely

Pesticide Registration Review Progress

- Issued 454 interim decisions (58% of total number of cases)
  - which explain any changes to what had been proposed, respond to significant public comments, and require registrants to submit any product label amendments needed to protect human health and the environment
- Issued 156 final decisions (20% of total number of cases),
  - which document proposed changes, respond to significant public comments, and require registrants to submit product label amendments needed to protect human health and the environment
- Of the 610 interim or final decisions, 140 cases resulted in cancellation of some or all uses (18% of total number of cases).

Wrap-Up/Next Meeting Date

- Wednesday, December 13, 2023, 9-11am EST

PRIA Points of Contact

- Steve Schaible, Senior Advisor, PRIA Coordinator: schaible.stephen@epa.gov
- OPP Ombudsperson Mailbox
  pesticidequestions@epa.gov
- RD Ombudsman:
  OPP_RD_Ombudsman@epa.gov
- BPPD:
  BPPDQuestions@epa.gov
- AD Ombudsman:
  pesticidequestions@epa.gov

Thank You!