



GPhA Quarterly Meeting

Program Update

Agenda

- MAPP On Communications
- Target Action Dates
- Productivity
- Follow-up Items



MAPP On Communications

MAPP Features

- Joint OPQ and OGD.
- Increased communications across Discipline PMs (including Div. of Filing), RBPMs and RPMs.
- Status updates “...of relevant review disciplines (including facility status)...”
- Notification of forthcoming letters.
(Labeling will call if 356(h) is old or no response received.)



Target Action Dates (TADs)

TADs for Incoming Responses to CRs and IRs

<i>Category</i>	Pre-cohort Year 3 ANDAs	Pre-cohort Year 3 ANDAs (expedited status)
Major (CR)	10 months	7 months
Minor (CR)	5 months	3 months
ECD	3 months	
IR	3 months	

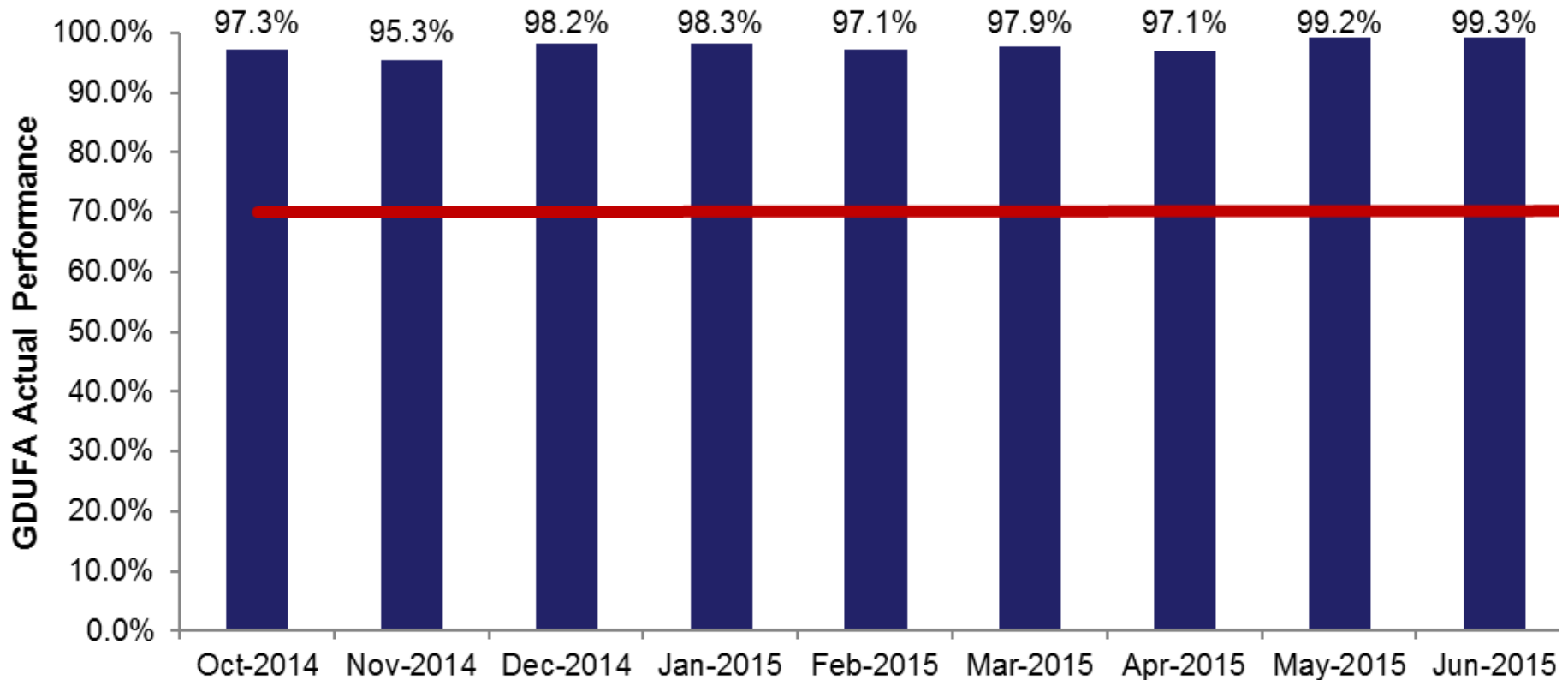
Your Help

- Please alert the RPM when the last IR to close out the IR set is being submitted. This will help trigger the new Target Action Date.
- If you are unsure that you received all the expected IRs, please contact your RPM.

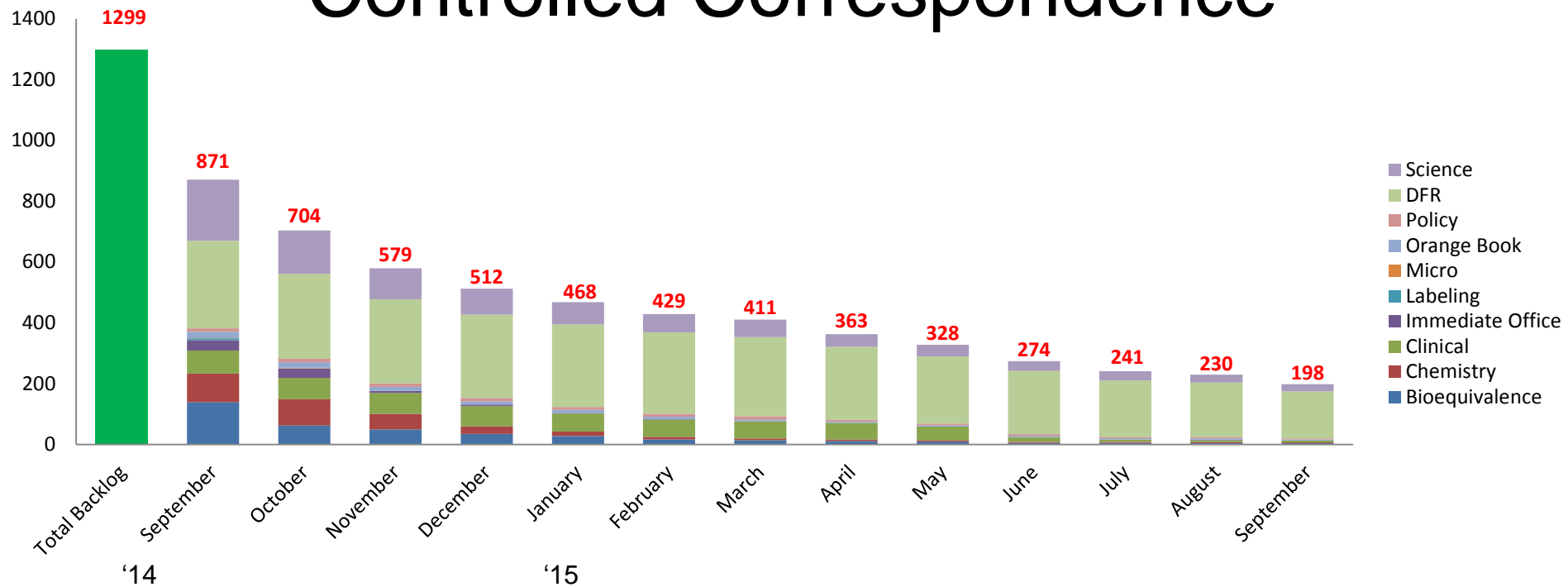


Productivity

GDUFA Performance Summary – Controlled Correspondence Report

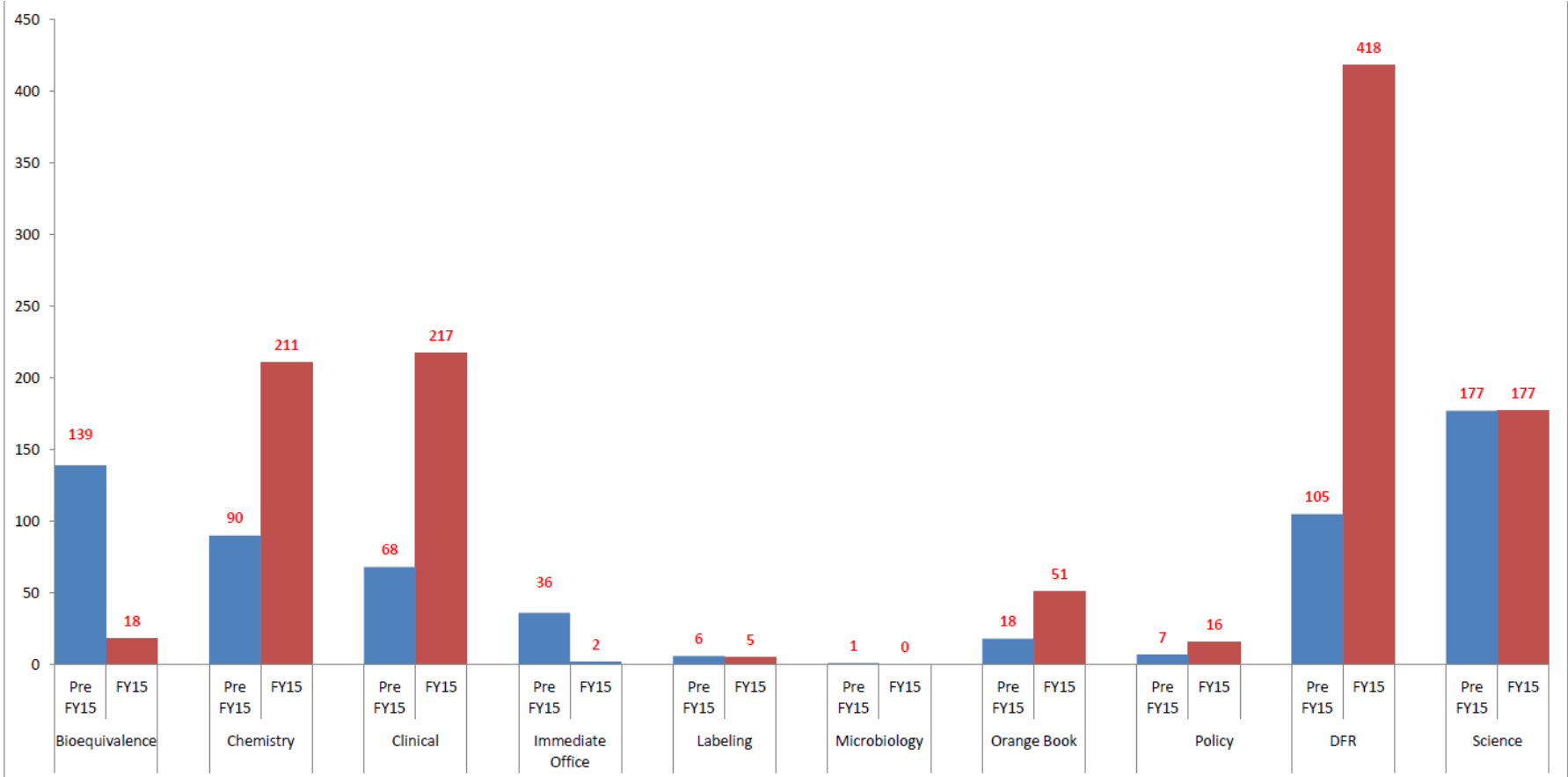


Backlog Performance Summary – Controlled Correspondence

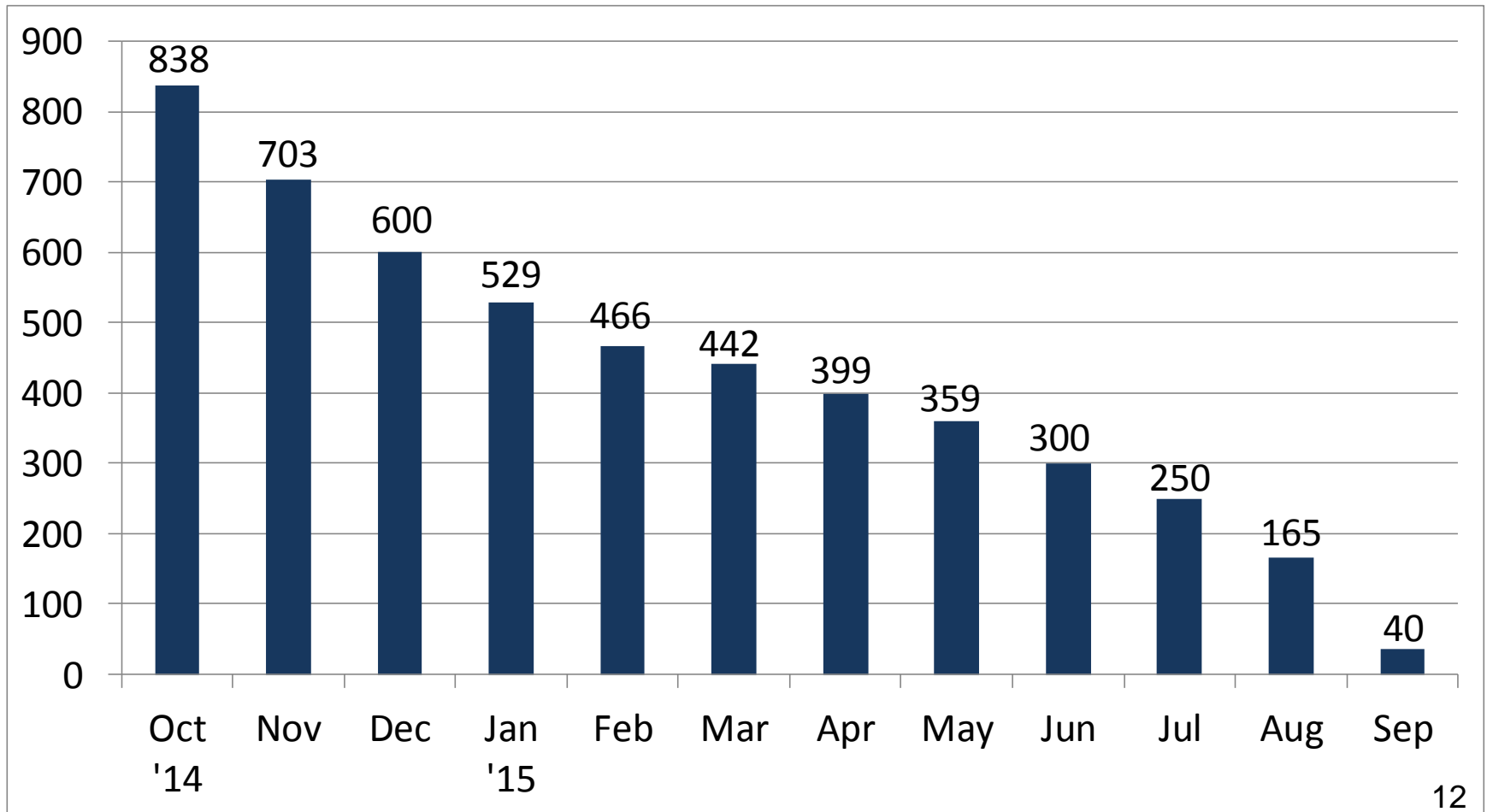




Controlled Correspondences Closed in FY 15



Filing Backlog (Pre-Y3)



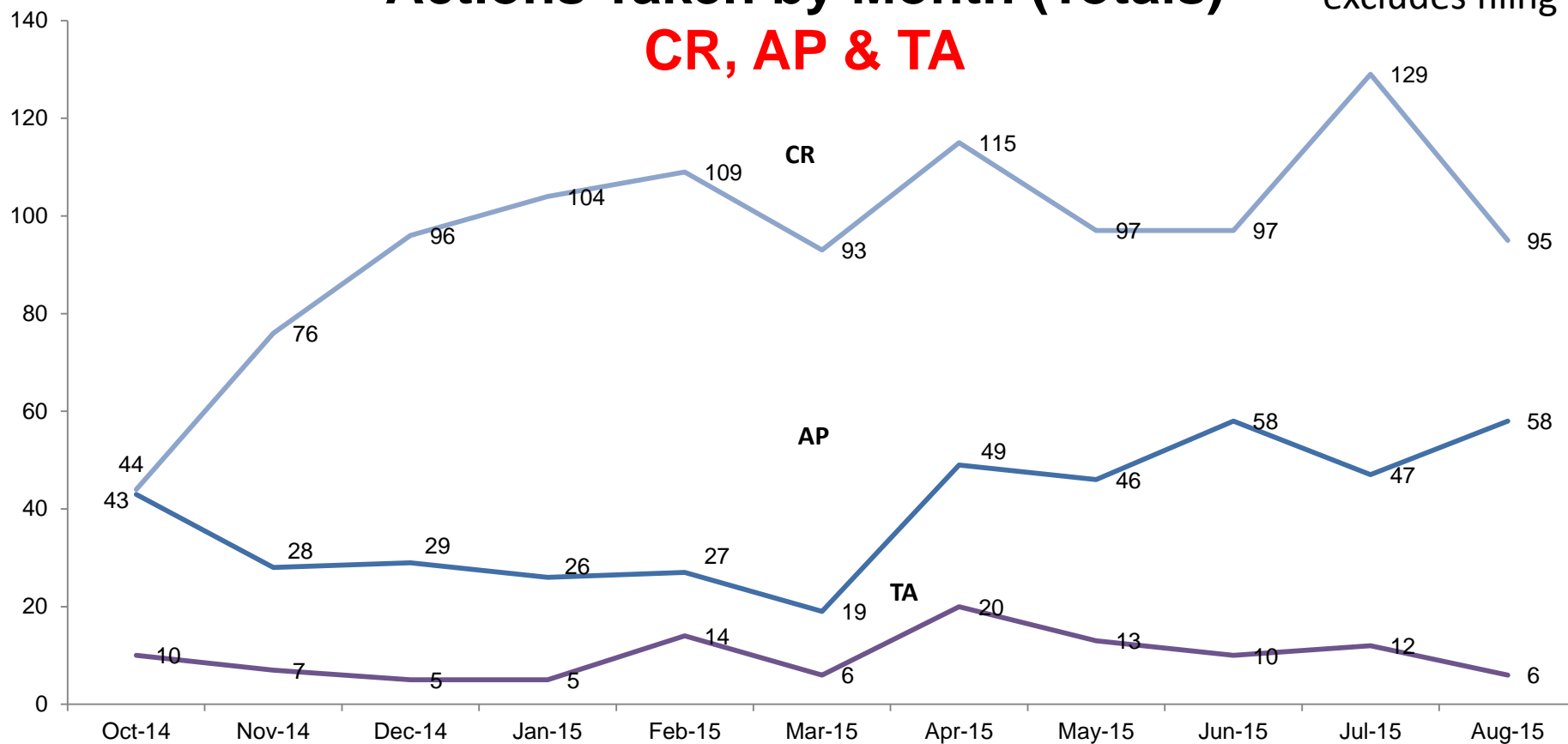
Filing Time Frames

- Current/GDUFA Year 3 submissions: 35 days.
- Pre-year 3 applications: about 40 left.
- Approximately 1,200 completed this year for Year 3 and the filing backlog.

FY15 Trends (ANDA Originals) – Actions Taken by Month (Totals)

CR, AP & TA

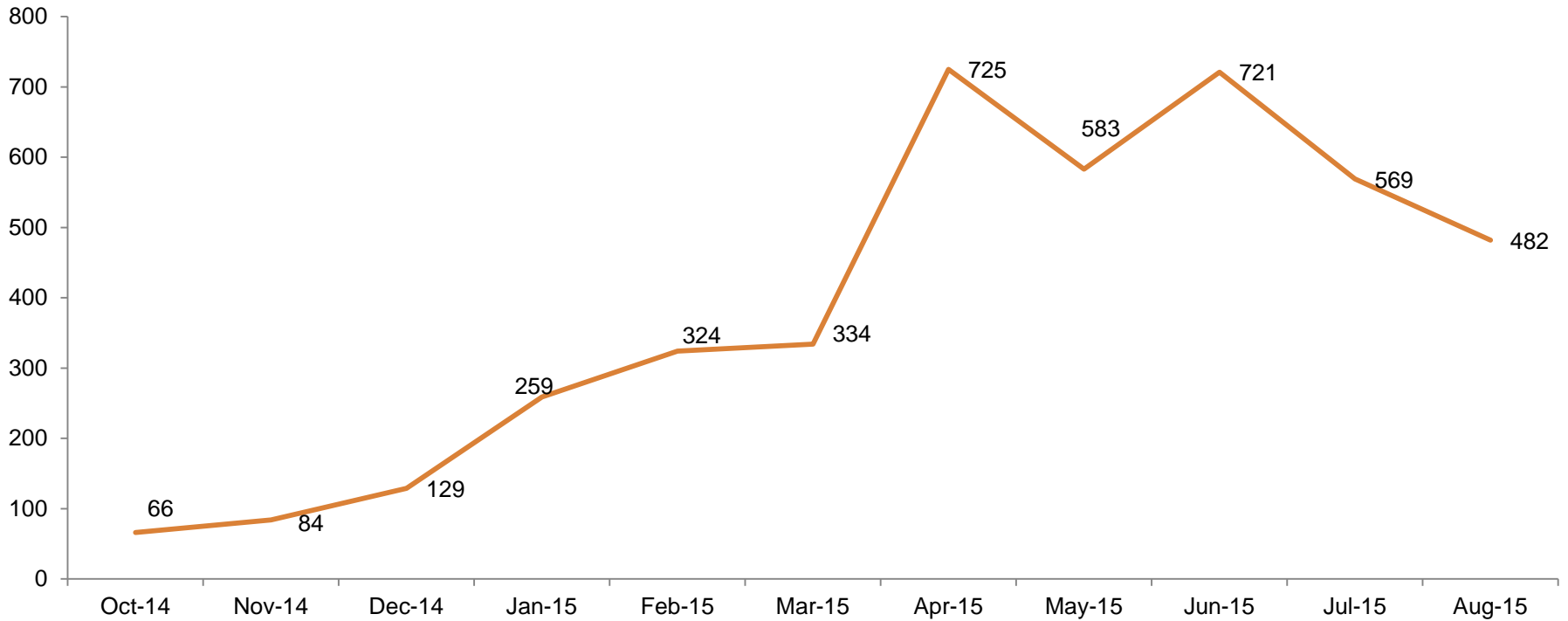
*excludes filing



FY15 Trends (ANDA Originals) – Actions Taken by Month (Totals)

*excludes filing

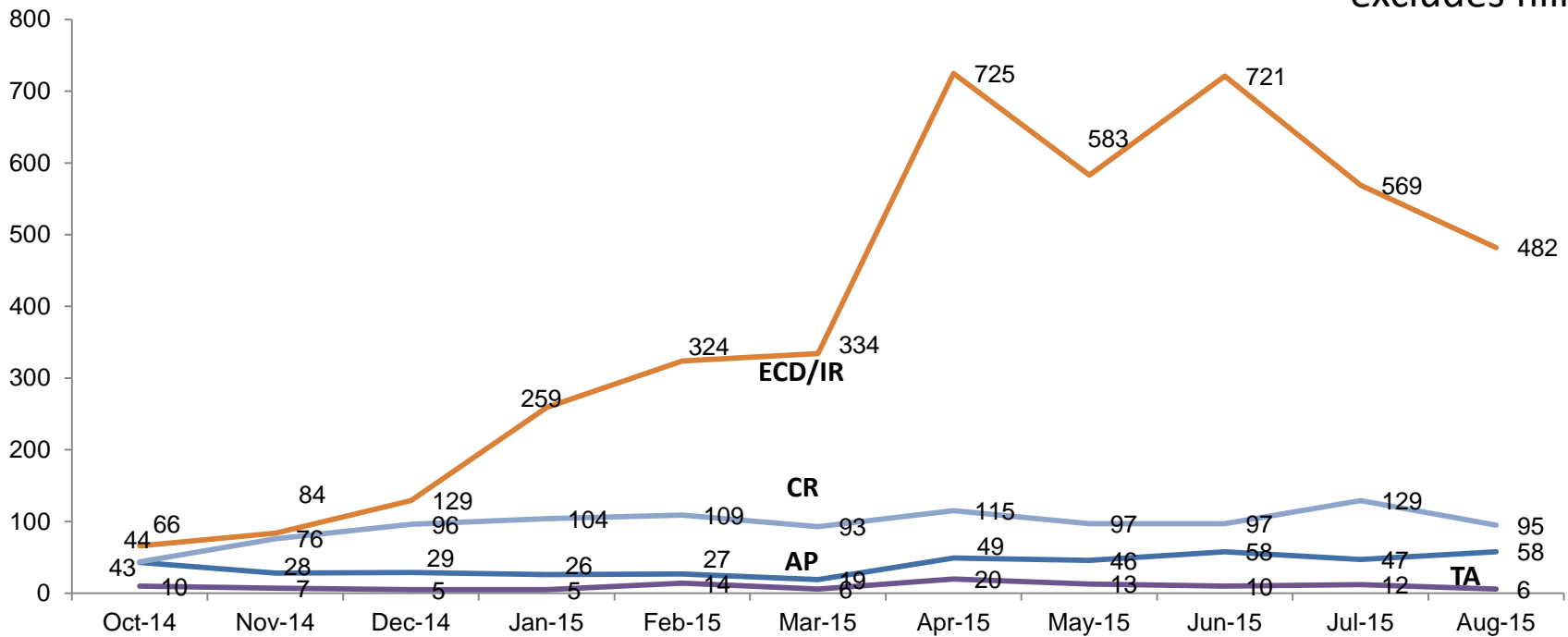
ECD/IR



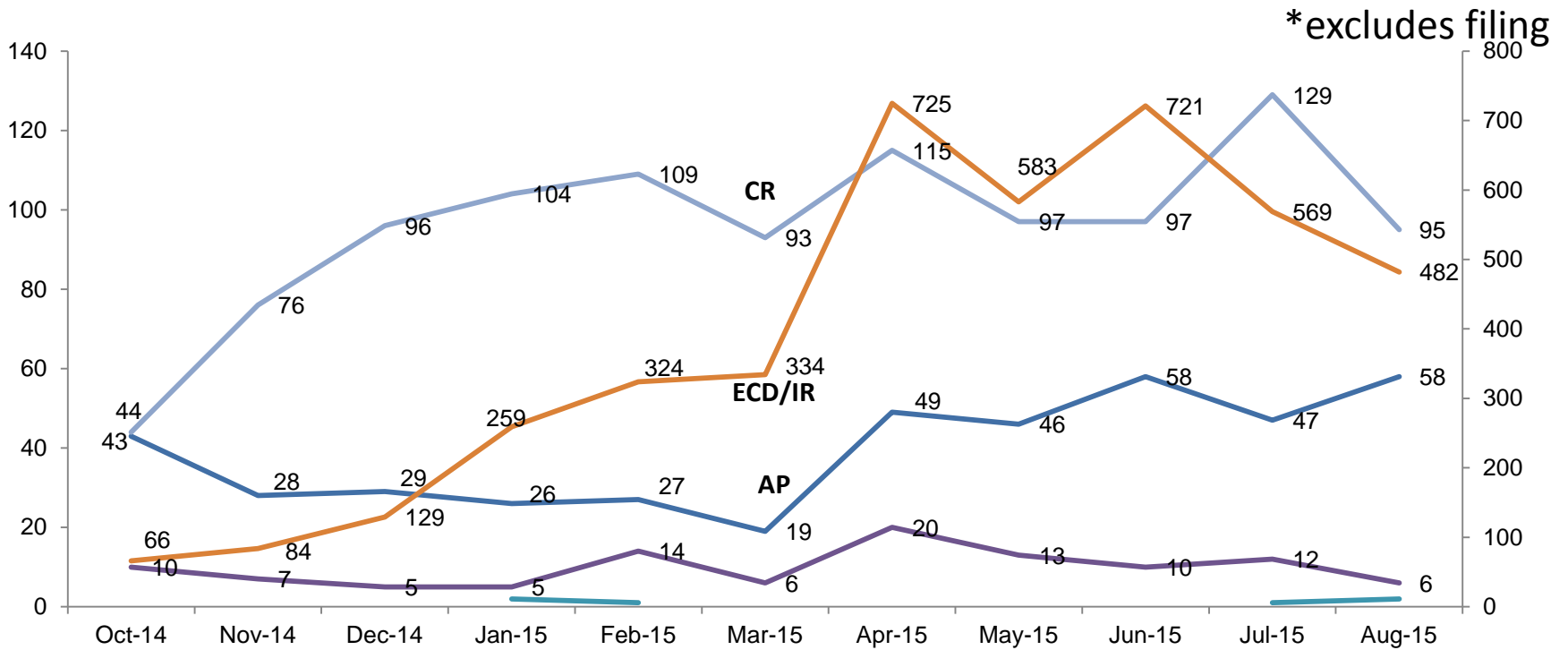
FY15 Trends (ANDA Originals) – Actions Taken by Month (Totals)

ECD/IR, CR, AP & TA

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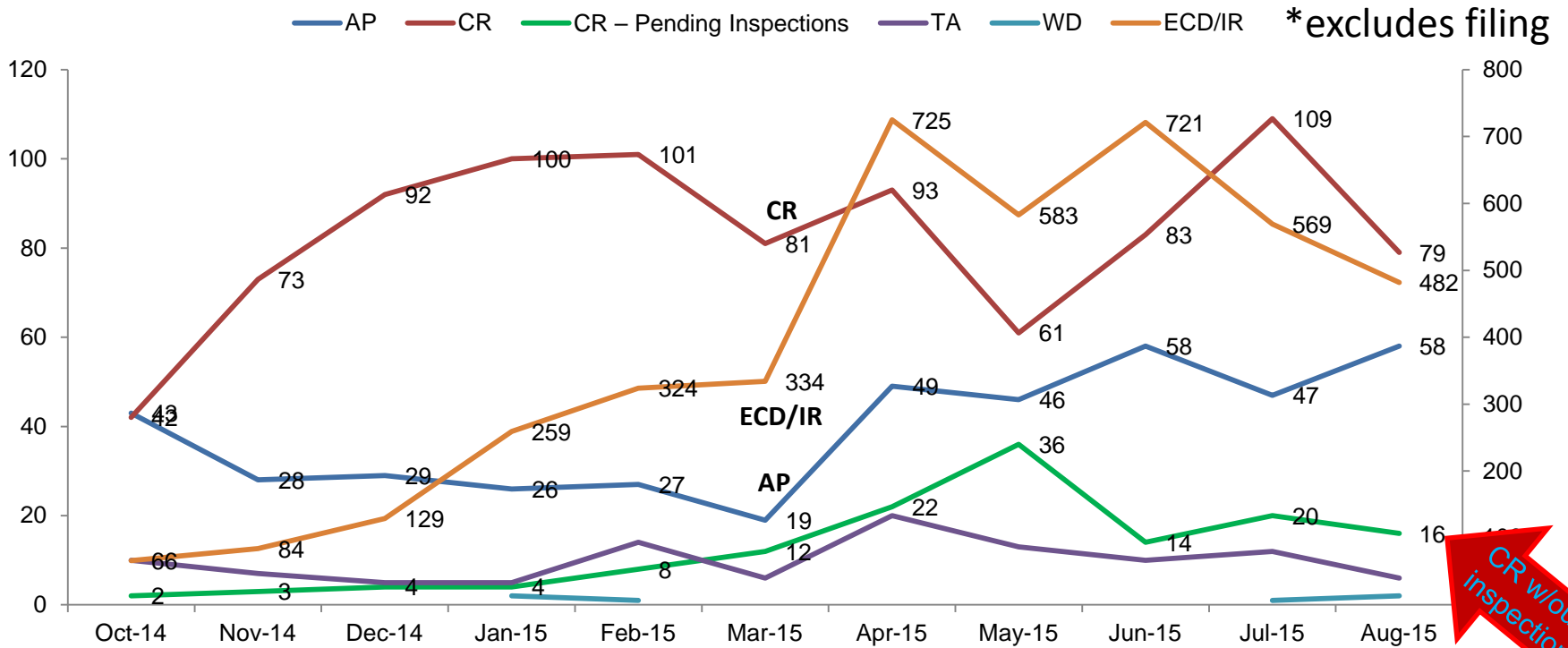


FY15 Trends (ANDA **Originals**) – Actions Taken by Month (Totals)



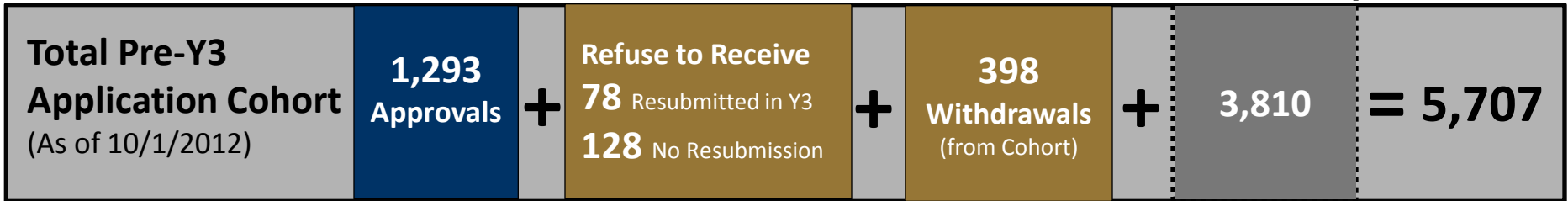
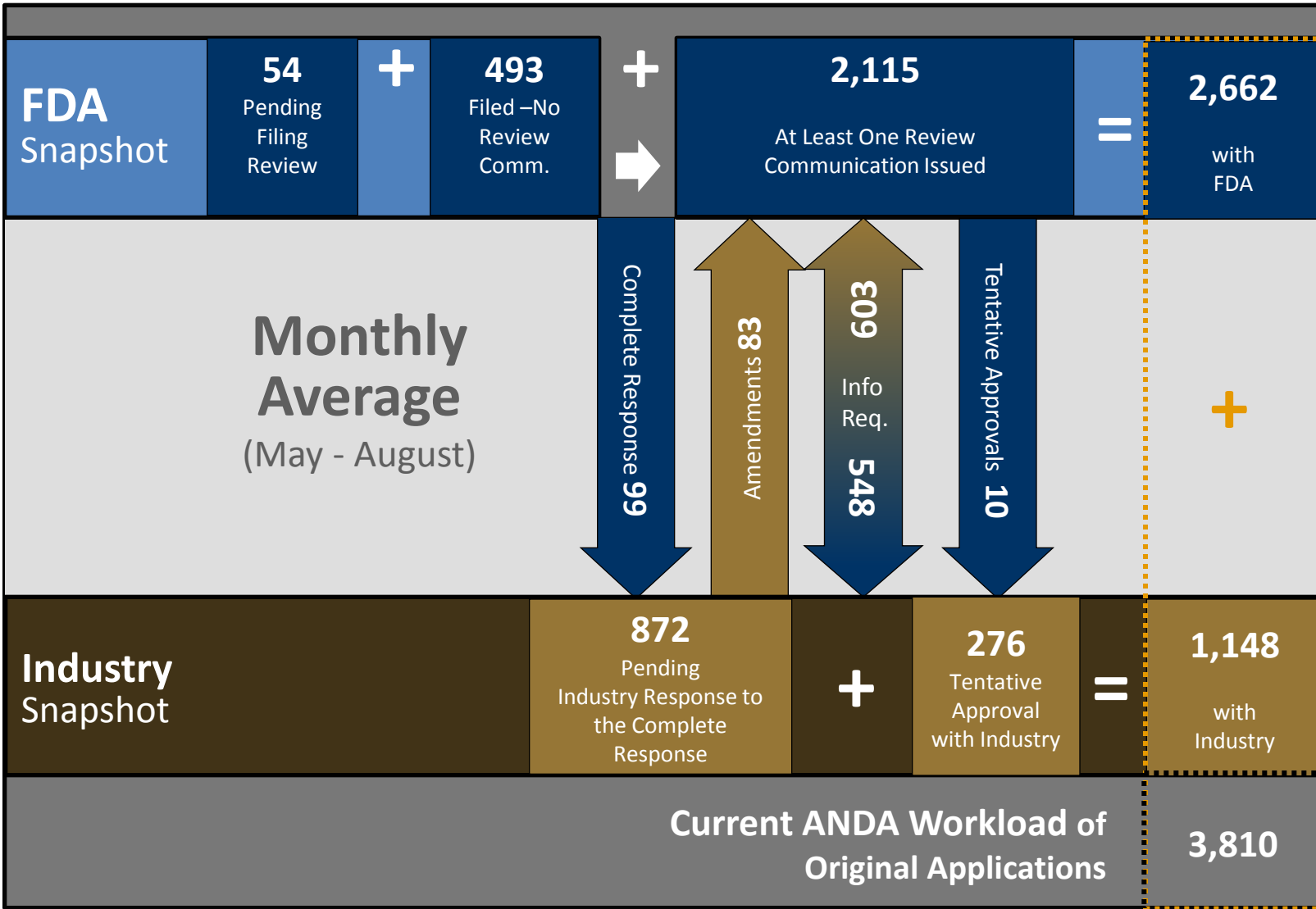
	Oct 2014	Nov 2014	Dec 2014	Jan 2015	Feb 2015	Mar 2015	Apr 2015	May 2015	Jun 2015	Jul 2015	Aug 2015	Grand Total
AP	43	28	29	26	27	19	49	46	58	47	58	401
CR	42	73	92	100	101	81	93	61	83	109	79	871
CR – Pending Inspections	2	3	4	4	8	12	22	36	14	20	16	135
TA	10	7	5	5	14	6	20	13	10	12	6	103
WD				2	1			1		1	2	5
ECD/IR	66	84	129	259	324	334	725	583	721	569	482	4276

FY15 Trends (ANDA Originals) – Actions Taken by Month (Totals)

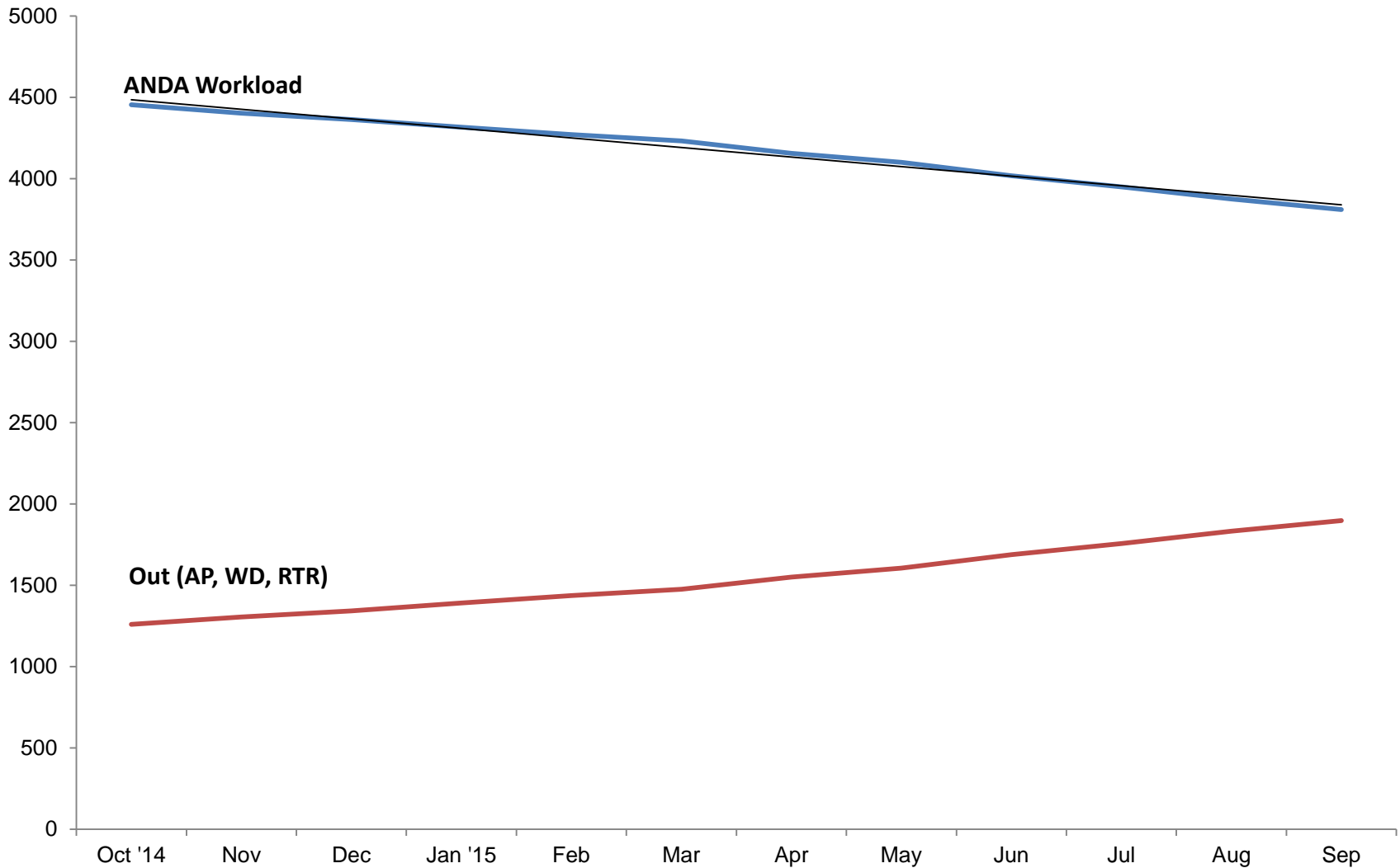


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CR w/out inspection

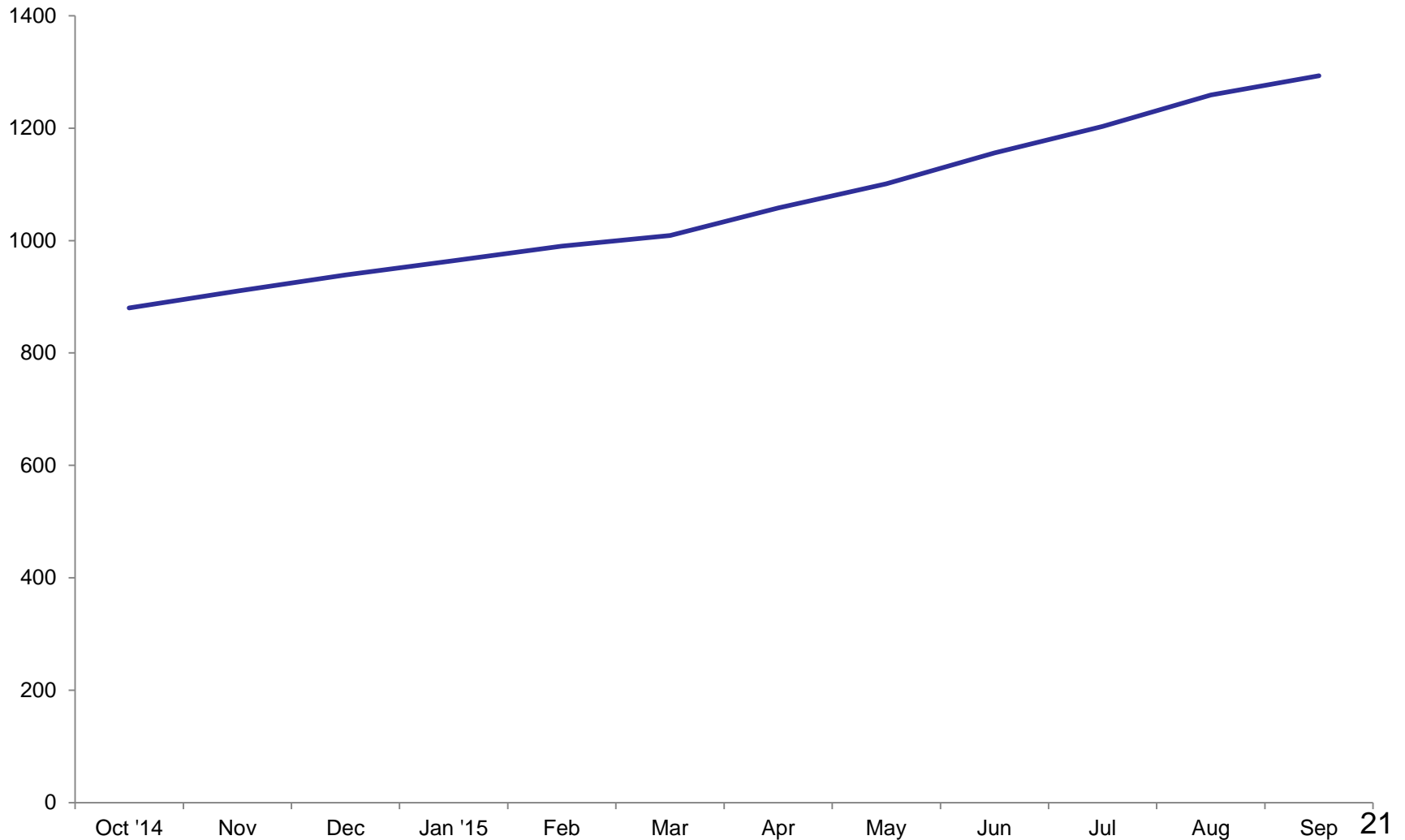


Pre Y3 Applications – Workload vs Outgoing



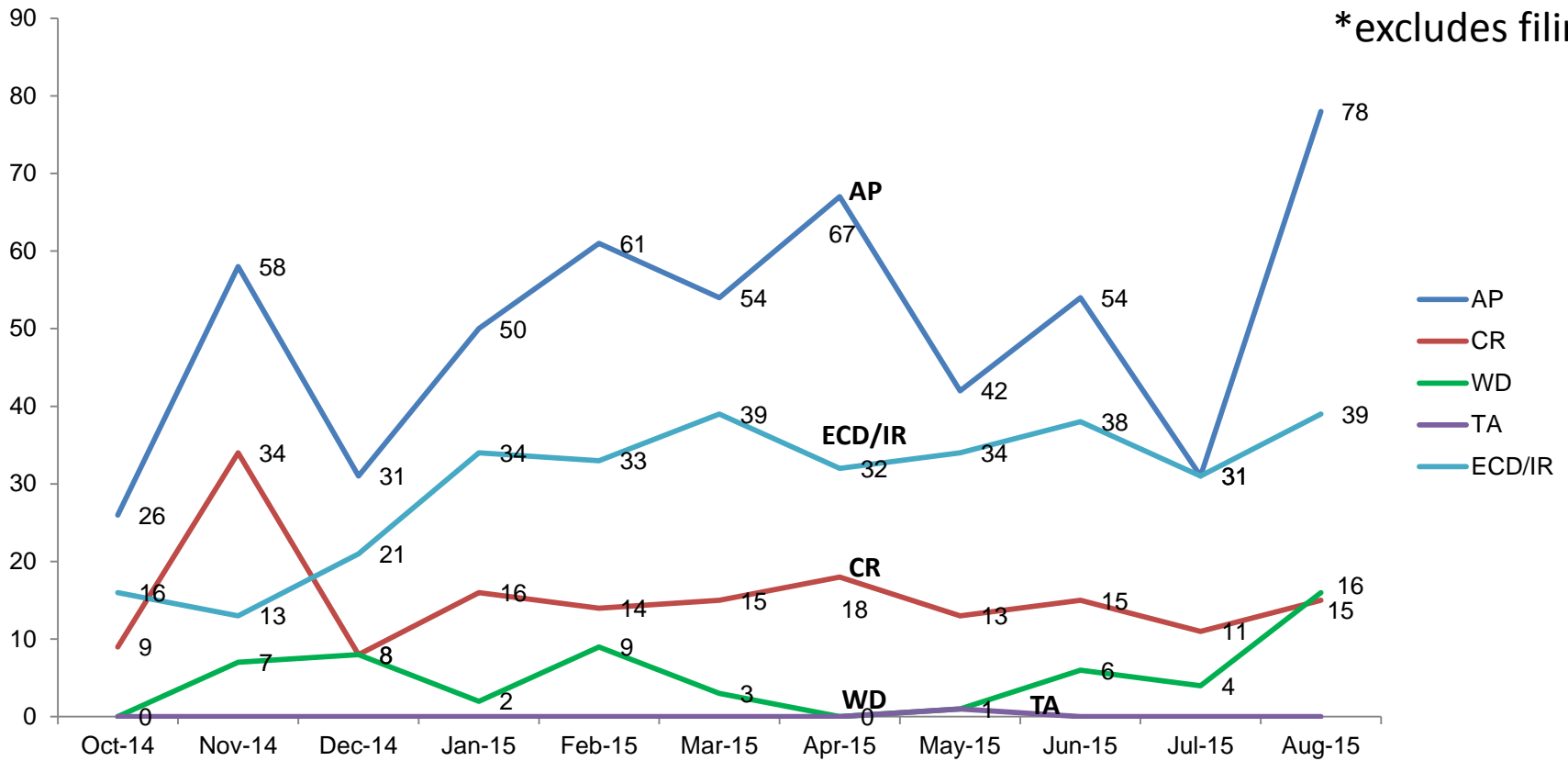


Pre-Y3 Approvals (cumulative)



FY15 Trends (ANDA PAS) – Actions Taken by Month (Totals)

*excludes filing



	Oct-2014	Nov-2014	Dec-2014	Jan-2015	Feb-2015	Mar-2015	Apr-2015	May-2015	Jun-2015	Jul-2015	Aug-2015	Grand Total
AP	26	58	31	50	61	54	67	42	54	31	78	552
CR	9	34	8	16	14	15	18	13	15	11	15	168
WD	0	7	8	2	9	3	0	1	6	4	16	56
TA	0	0	0	0	0	0	0	0	1	0	0	1
ECD/IR	16	13	21	34	33	39	32	34	38	31	39	330



Follow-up Items

Filing Reviews

- Don't want to Refuse to Receive ANDAs.
 - Extra work and resources.
 - Delays product availability.
- Must be fair to all companies – finance/resource perspective.
- Must be consistent across companies – policy perspective.
- Must support the review disciplines.

Filing Reviews (cont.)

- Provide clear scientific justification for any deviations from guidances.
- Tie goes to the applicant at the time of filing.

Rescissions

- Rescissions are evaluated for lessons learned.
- Rescissions reset the clock and we must make up the time.

Deficiency Education

- We will share more information about common RTR issues.
- We will share more information and provide more explanation about DMF deficiencies and Initial Completeness Assessments.

Controlled Correspondence Future

- Continue efforts to meet the goals.
- Continue to work through the backlog.
- Improve completeness of the response.

Additional

- Carefully consider the 356(h) contact – CEO may not always be the best contact to facilitate rapid communications.
- Please update contact changes.
- Please make sure amendment cover letters clearly state the type of amendment being submitted to facilitate coding and triaging by FDA.
- Please enter correct FEIs on the 356(h).



Questions?