ANDA Performance/ Operations Update

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CDER Small Business and Industry Assistance (SBIA) Regulatory Education for Industry (REdI): Generic Drugs

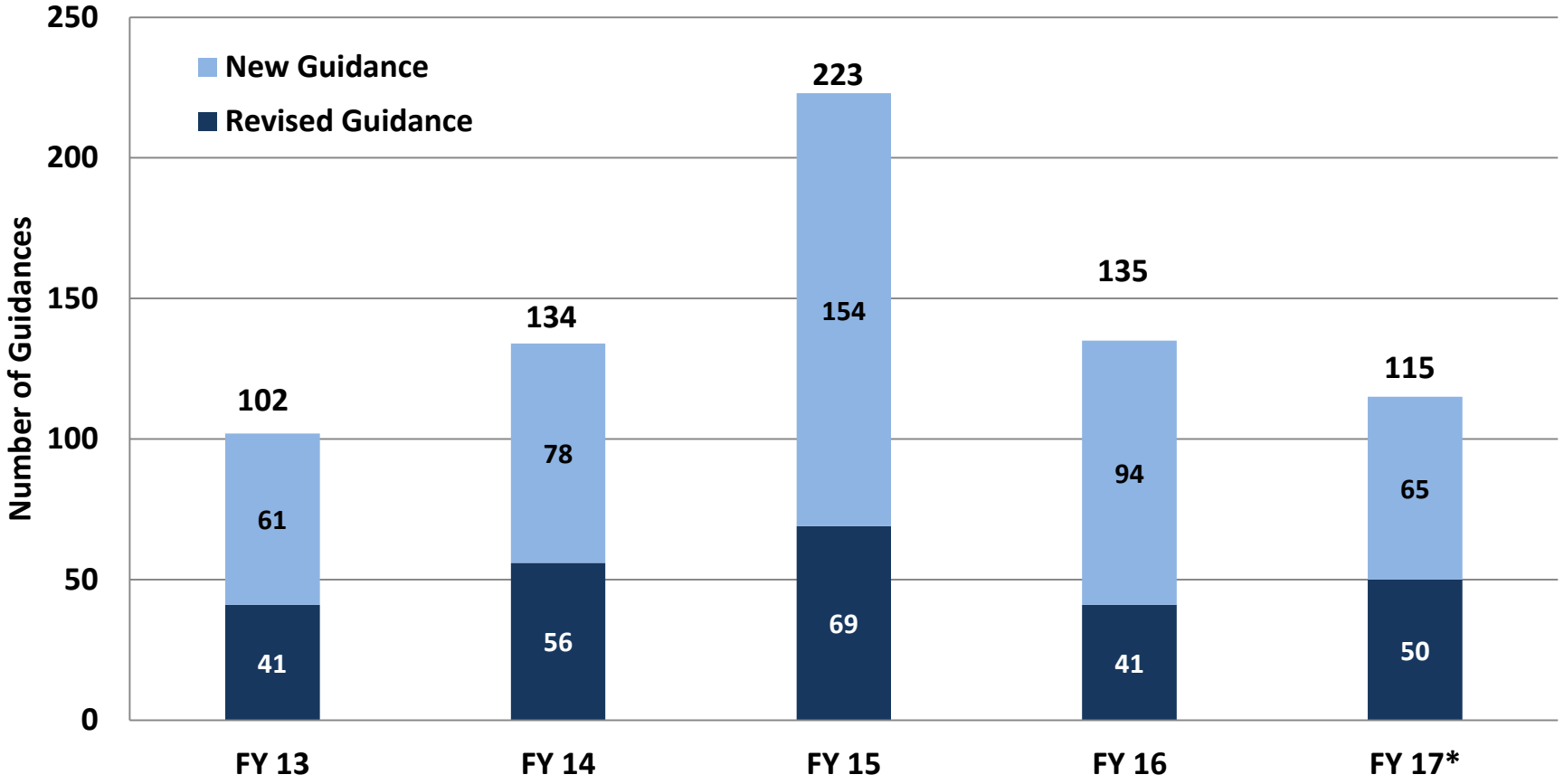
April 4, 2017

How is the ANDA program doing and what is the real story behind the numbers?

Agenda

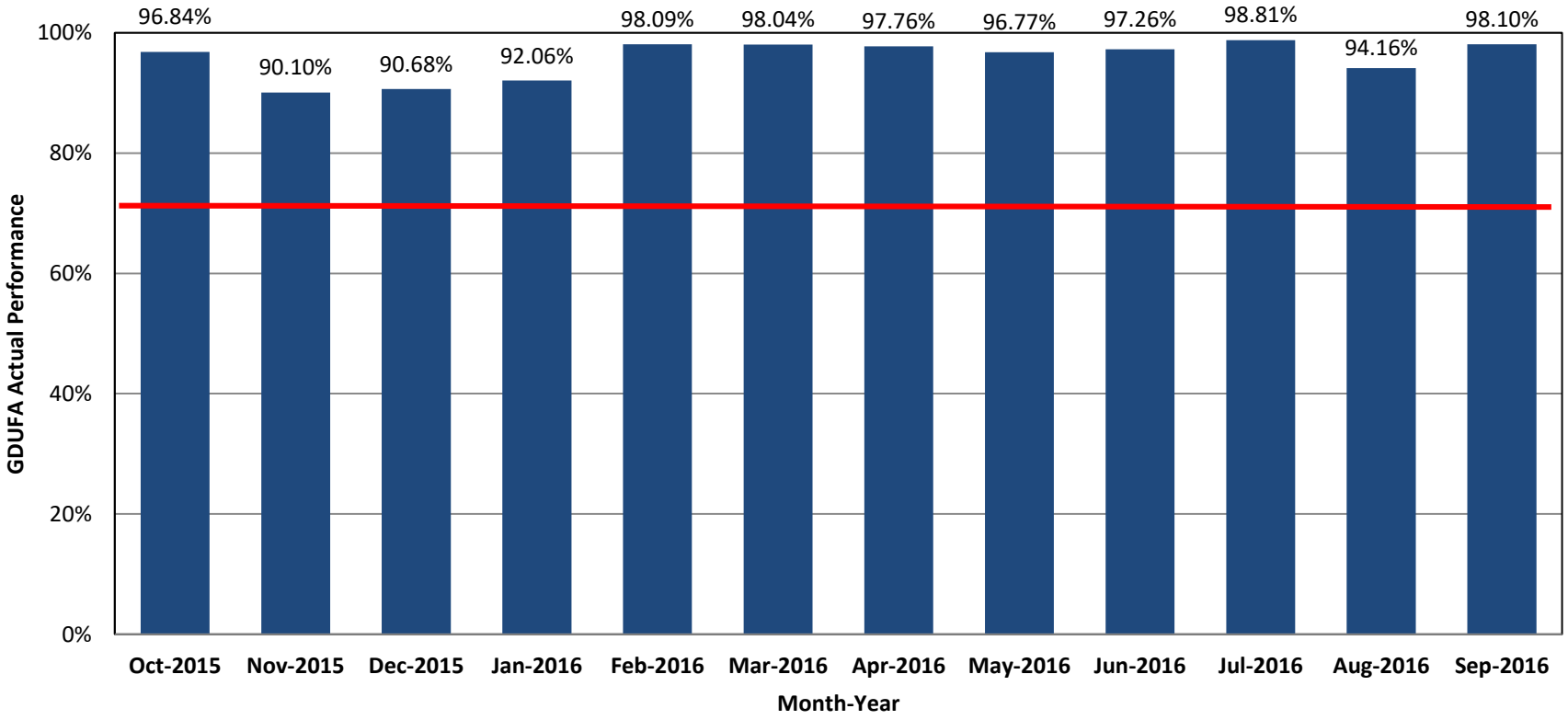
- Pre-submission
- Originals
- Prior-Approval Supplements (PAS)
- GDUFA II

Product-Specific Guidances



GDUFA Goal: Controlled Correspondence

Controlled Correspondence
FY 16 GDUFA Performance by FDA Receipt Date – All Disciplines



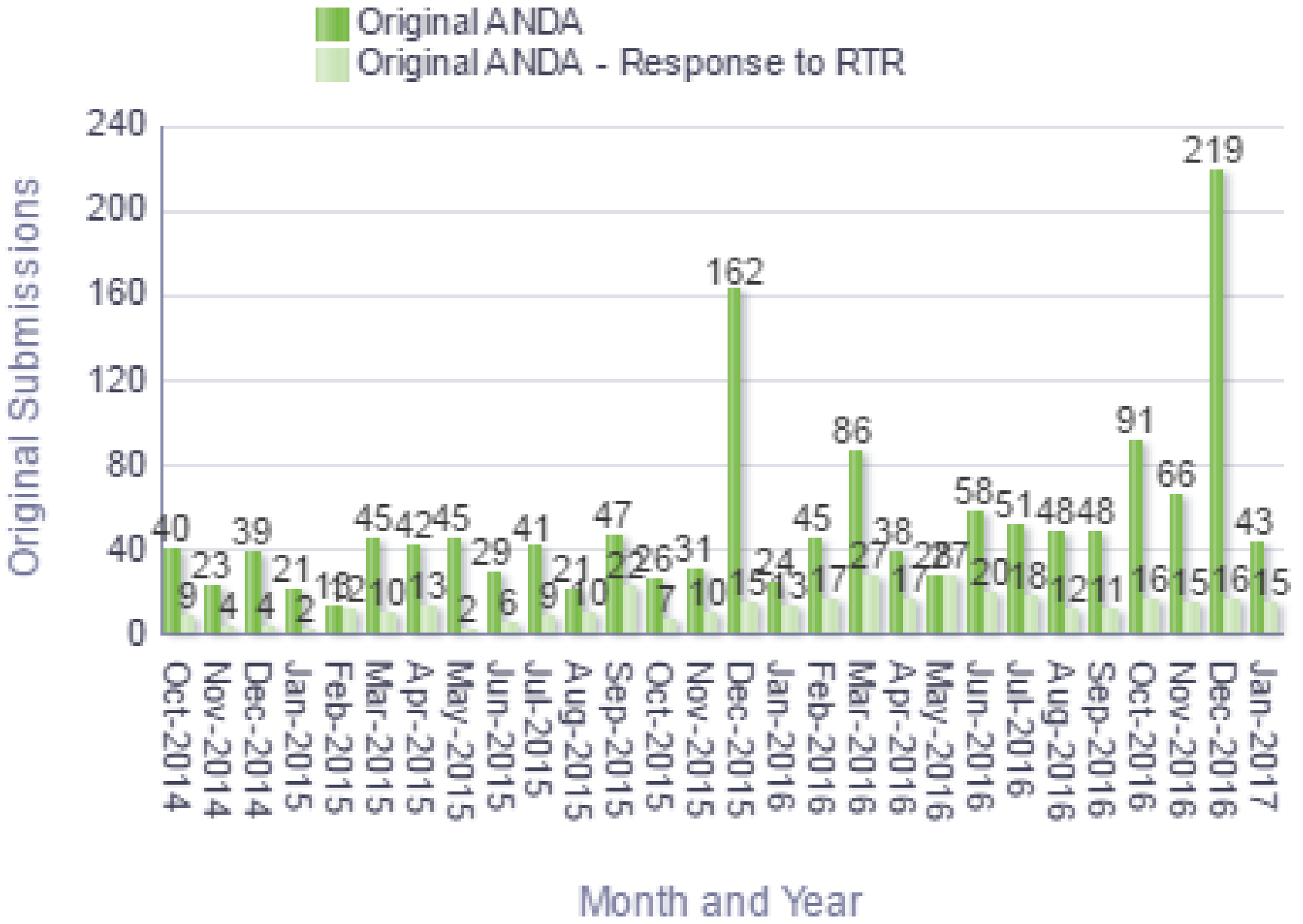
* Goal dates provided on submissions received through February 2016, as those are the goal dates that have actually accrued. The cohort data is not mature enough to report on whole year data

*As of 1/1/17. Numbers are based on preliminary data that will be reviewed and validated for official reporting purposes.
http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/ucm375079.htm

Agenda

- Pre-submission
- **Originals**
- Prior-Approval Supplements (PAS)
- GDUFA II

Original Submissions/Receipts

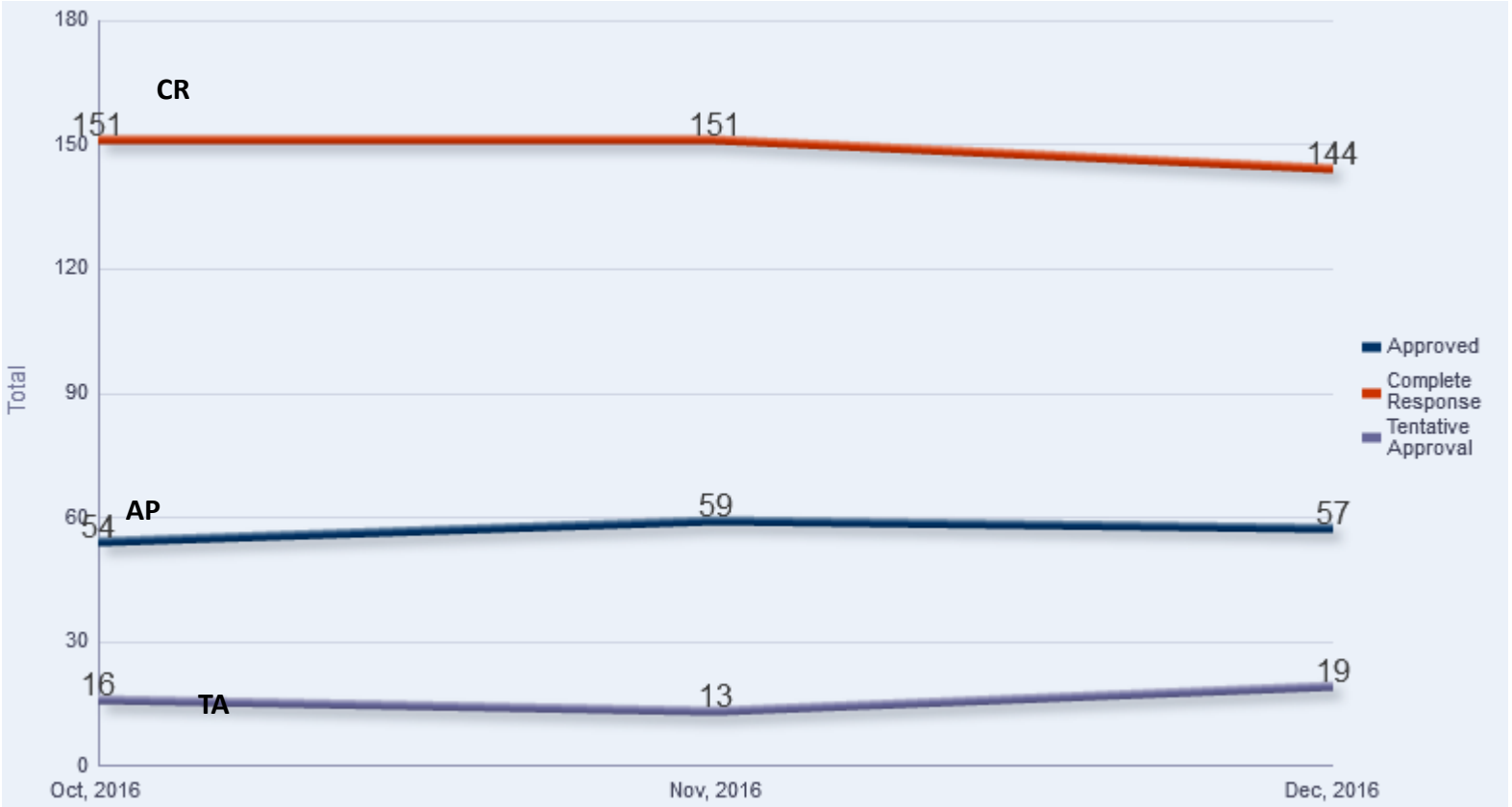


FY17 Trends (ANDA Originals) – Actions Taken by Month (Totals)

CR = Complete Response

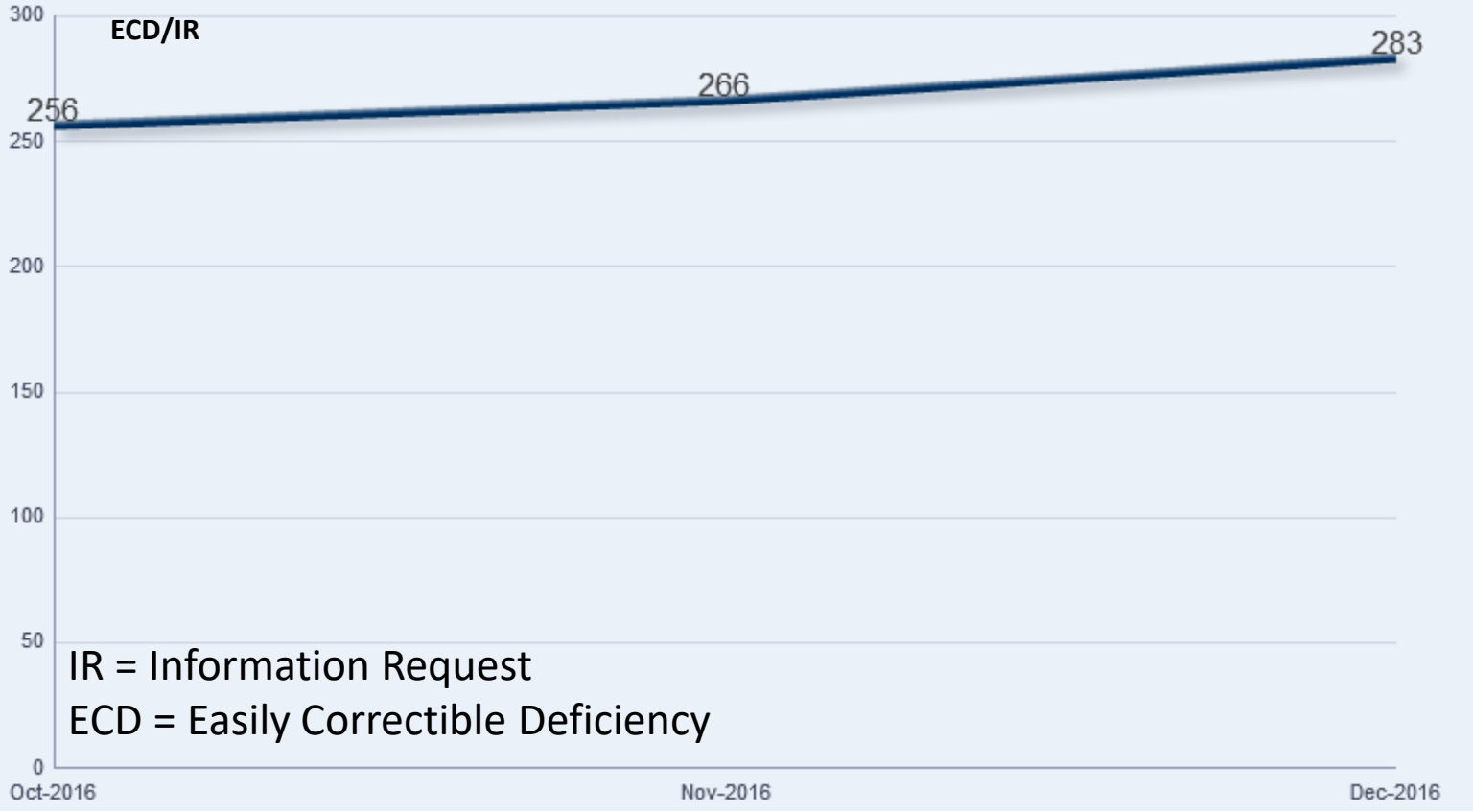
AP = Approval

TA = Tentative Approval



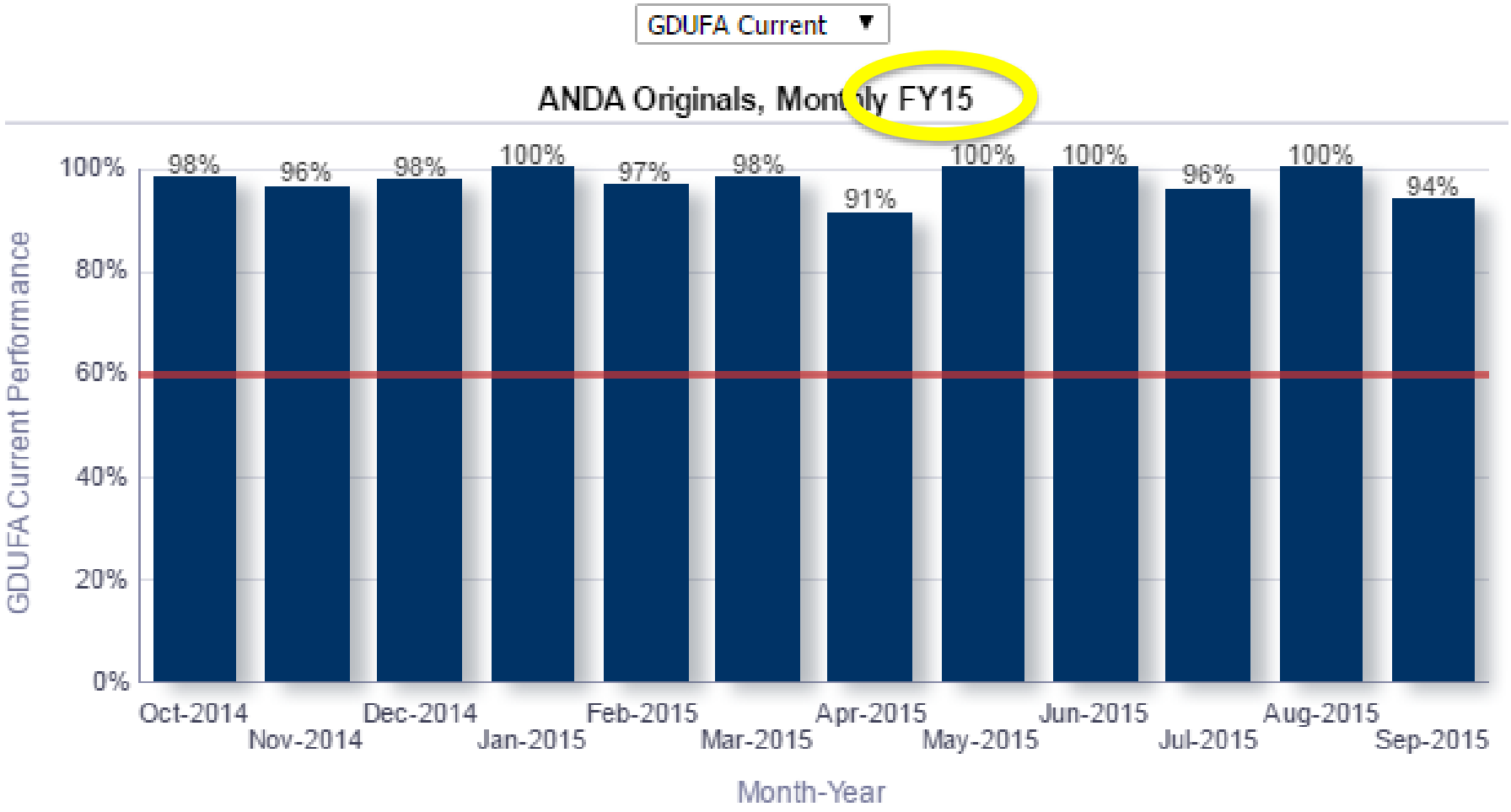
Submission Status	Oct, 2016	Nov, 2016	Dec, 2016	Grand Total
Approved	54	59	57	**170**
Complete Response	147	148	142	**437**
Complete Response Pending Inspections	4	3	2	**9**
Tentative Approval	16	13	19	**48**

FY16 Trends (ANDA Originals) – ECD/IRs Issued by Month *excludes filing

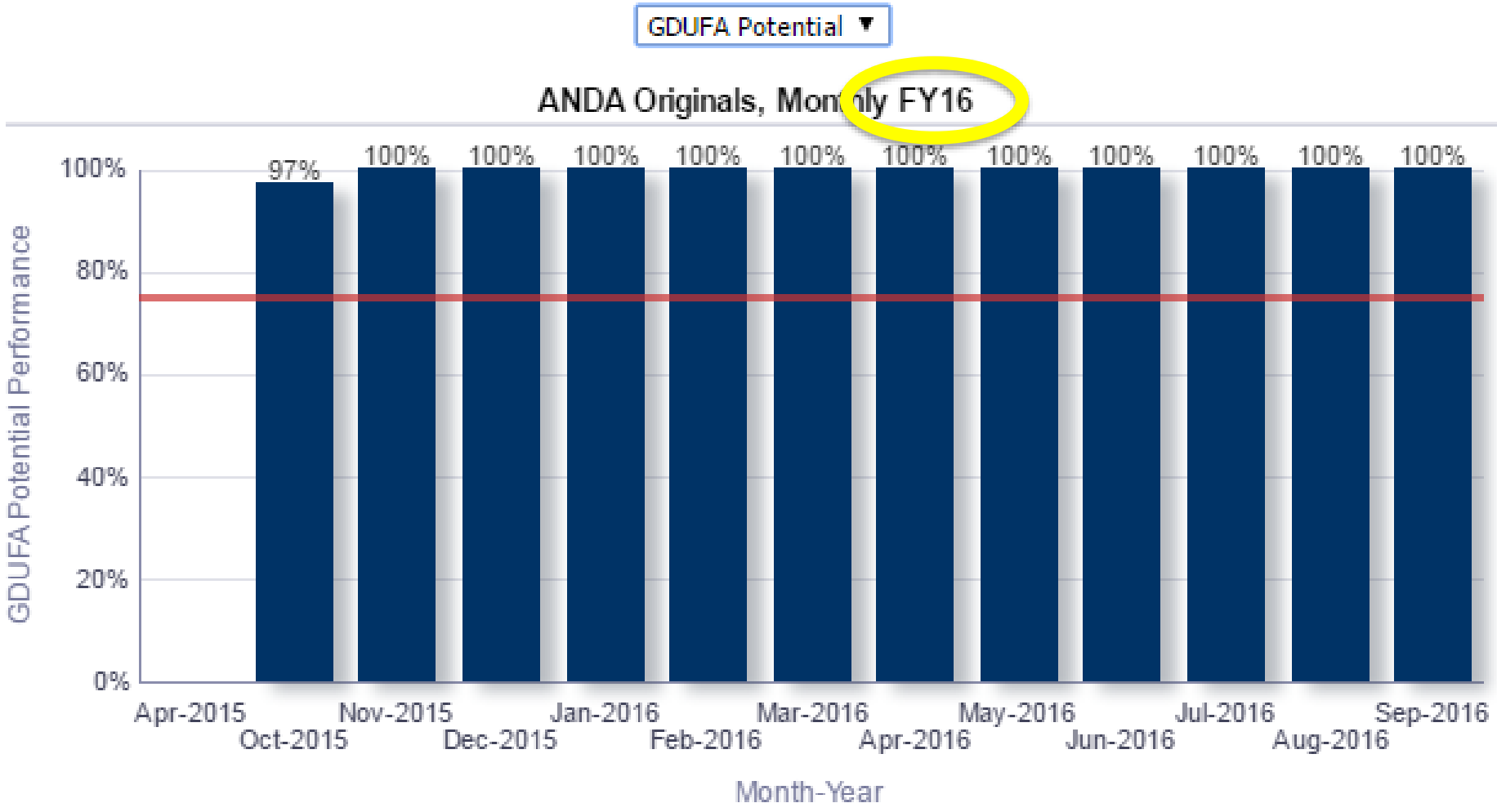


	Oct-2016	Nov-2016	Dec-2016
ECD/IR Count	256	266	283

Originals vs GDUFA Goals: FY 15



Originals vs GDUFA Goals: FY 16



Orig. ANDA Goal Misses

~ Delay	Status	Action Taken: Reason Goal Missed
1 day	TA	legal update needed from applicant and facilities check
1 day	CR	applicant's contractor had an issue
1 day	AP	time to complete the full approval package
10 days	CR	inspection need emerged during the review
12 days	TA	difficulty in completing inspections
13 days	CR	facility issues emerged near the goal date
14 days	AP	goal could have been met, but then applicant would not have been able to have completed a timely request for approval
15 days	CR	facility issues emerged near the goal date
29 days	CR	policy issue outside of OGD/OPQ jurisdiction
29 days	CR	policy issue outside of OGD/OPQ jurisdiction
83 days	CR	cross-Center consult needed

AP = Approval

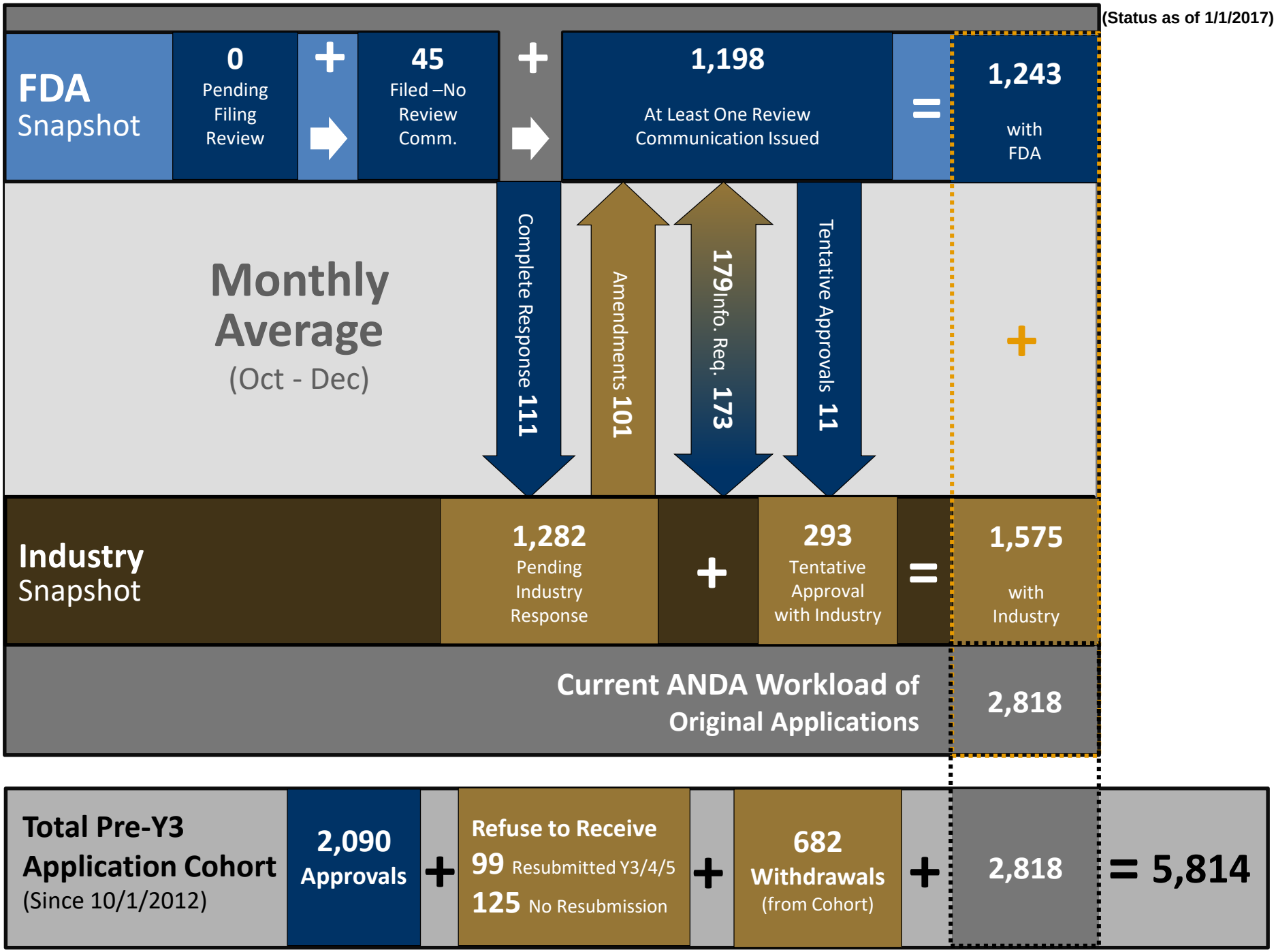
TA = Tentative Approval

CR = Complete Response

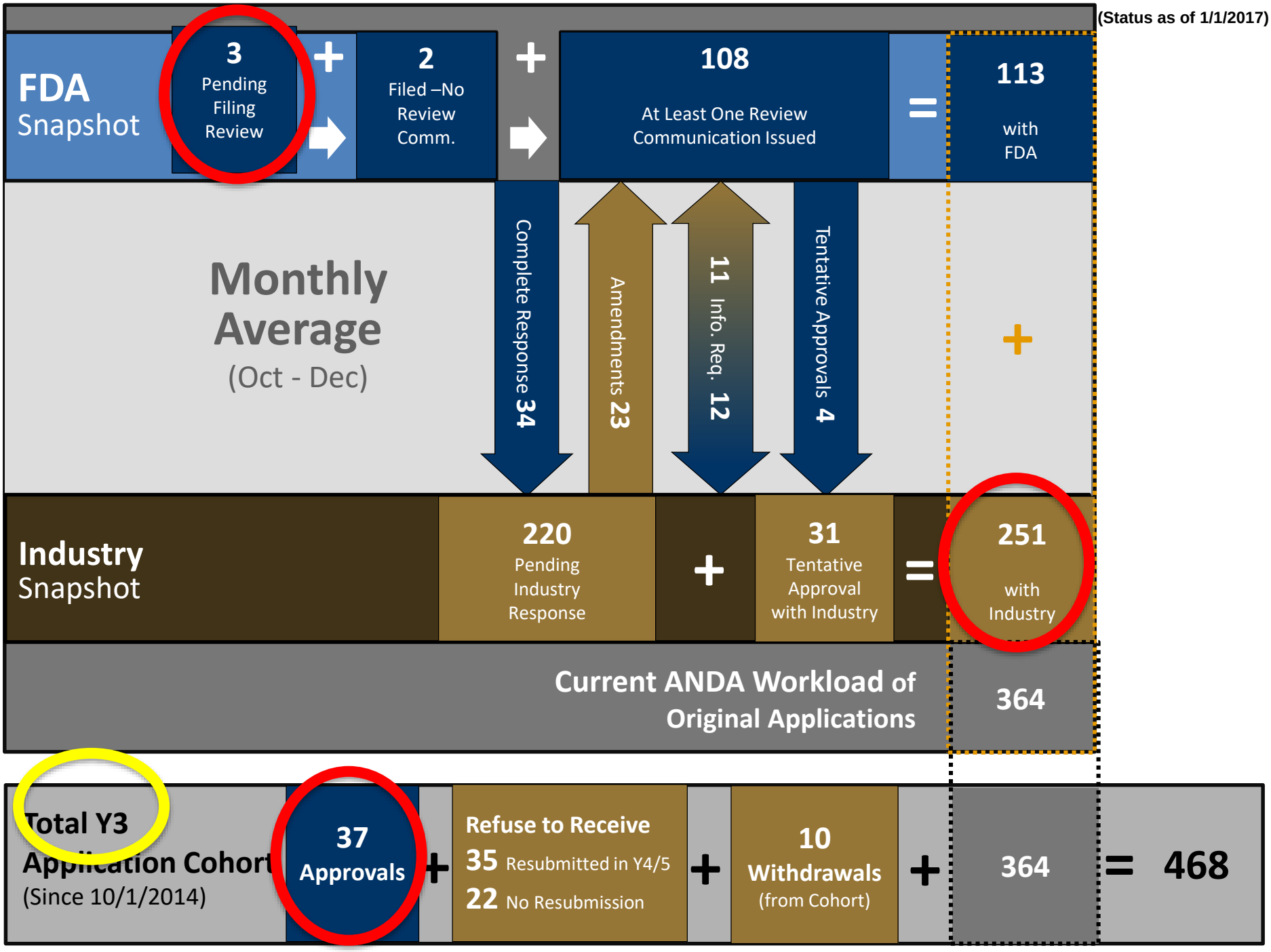
GDUFA I "Backlog"

- 2866 originals (not AP, not TA, not WD on October 1. 2013/Day 1 of GDUFA I)
  - Goal: 90% reviewed by Oct. 1, 2017
  - **Current status: >95% regulatory action (often multiple) issued**
  - Remaining: 137
    - With FDA: 130 (most are policy & facility issues)
    - Still w/ Applicant: 7 (low interest???)

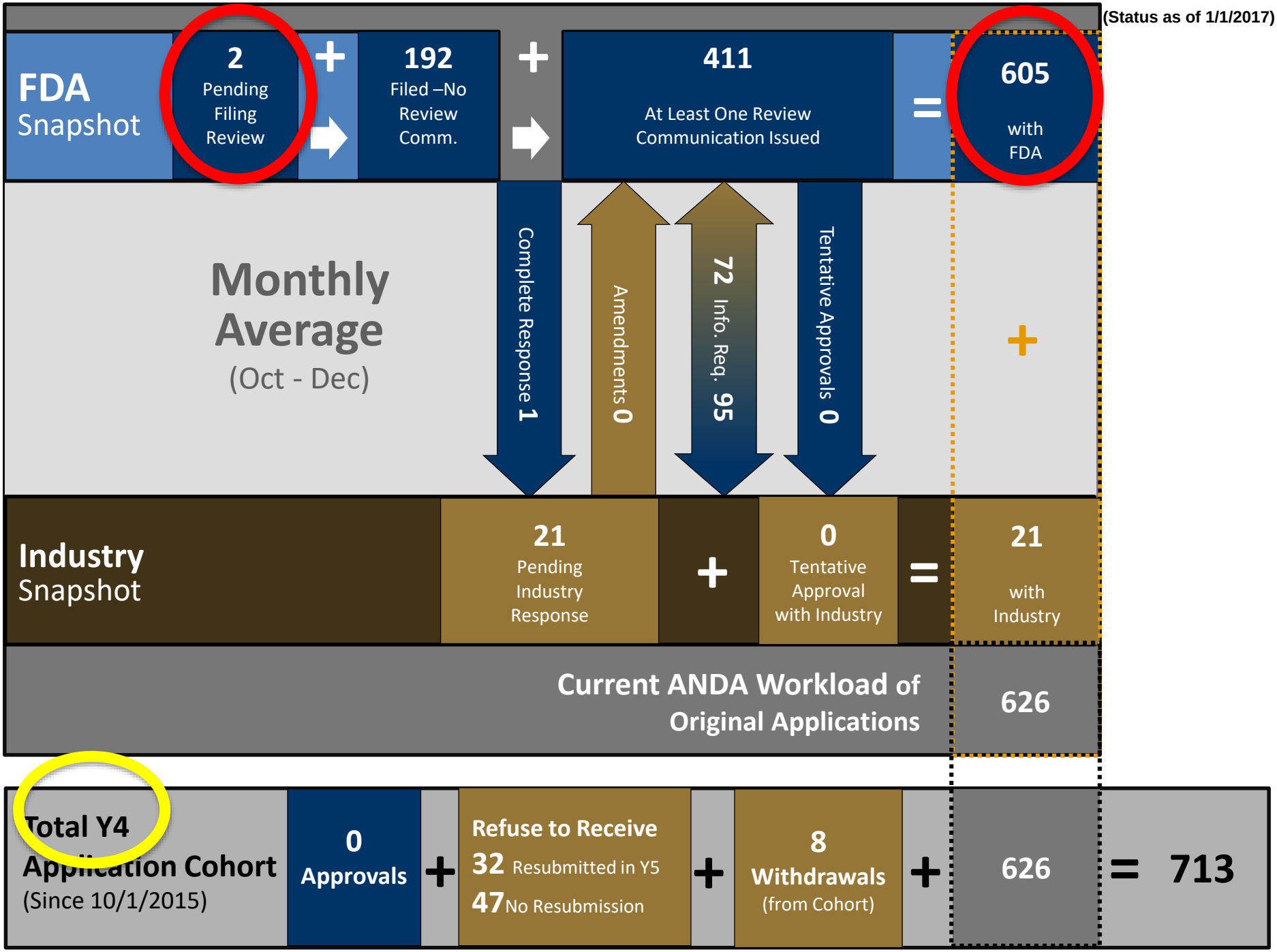
(Status as of 1/1/2017)



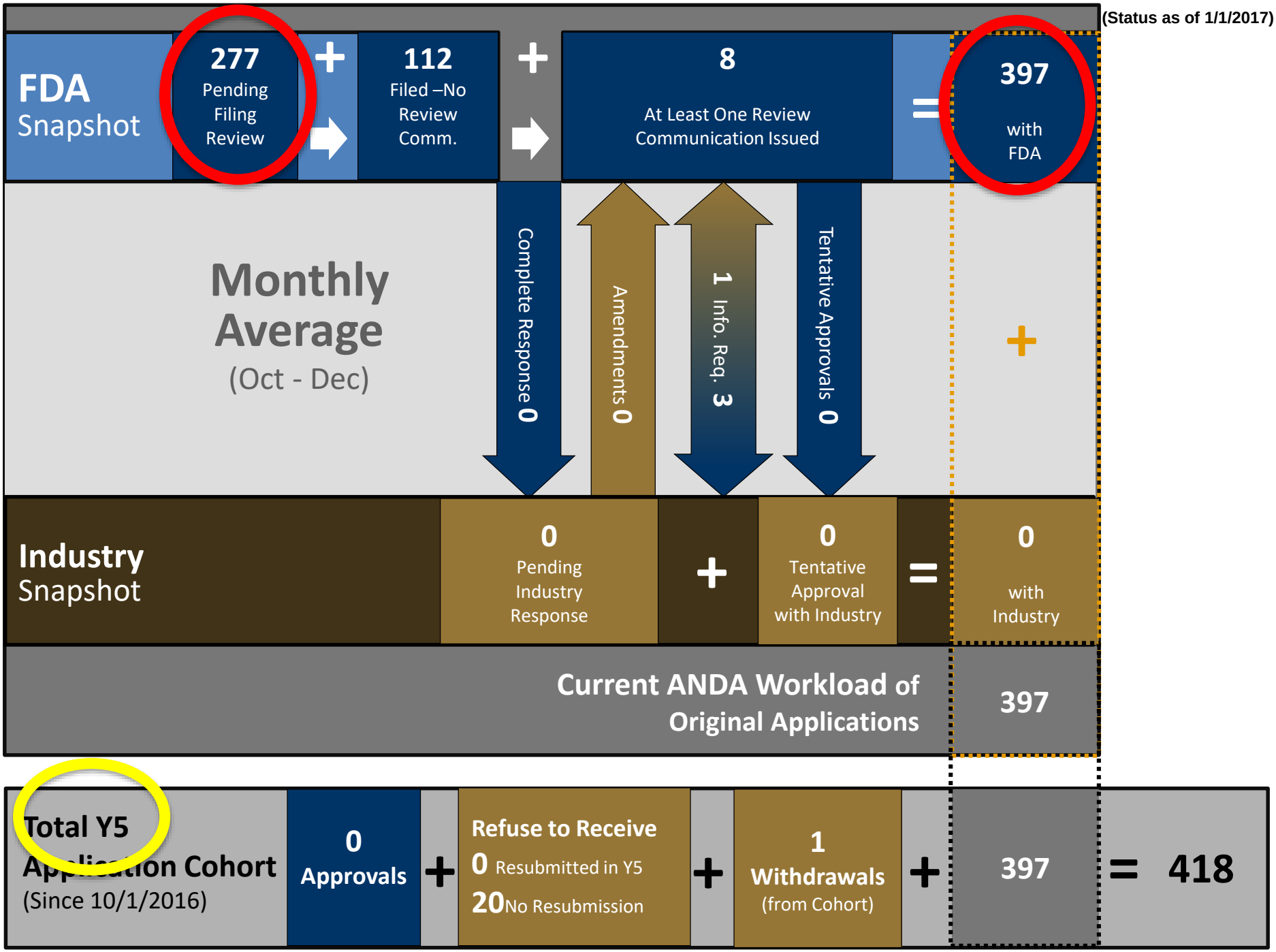
(Status as of 1/1/2017)



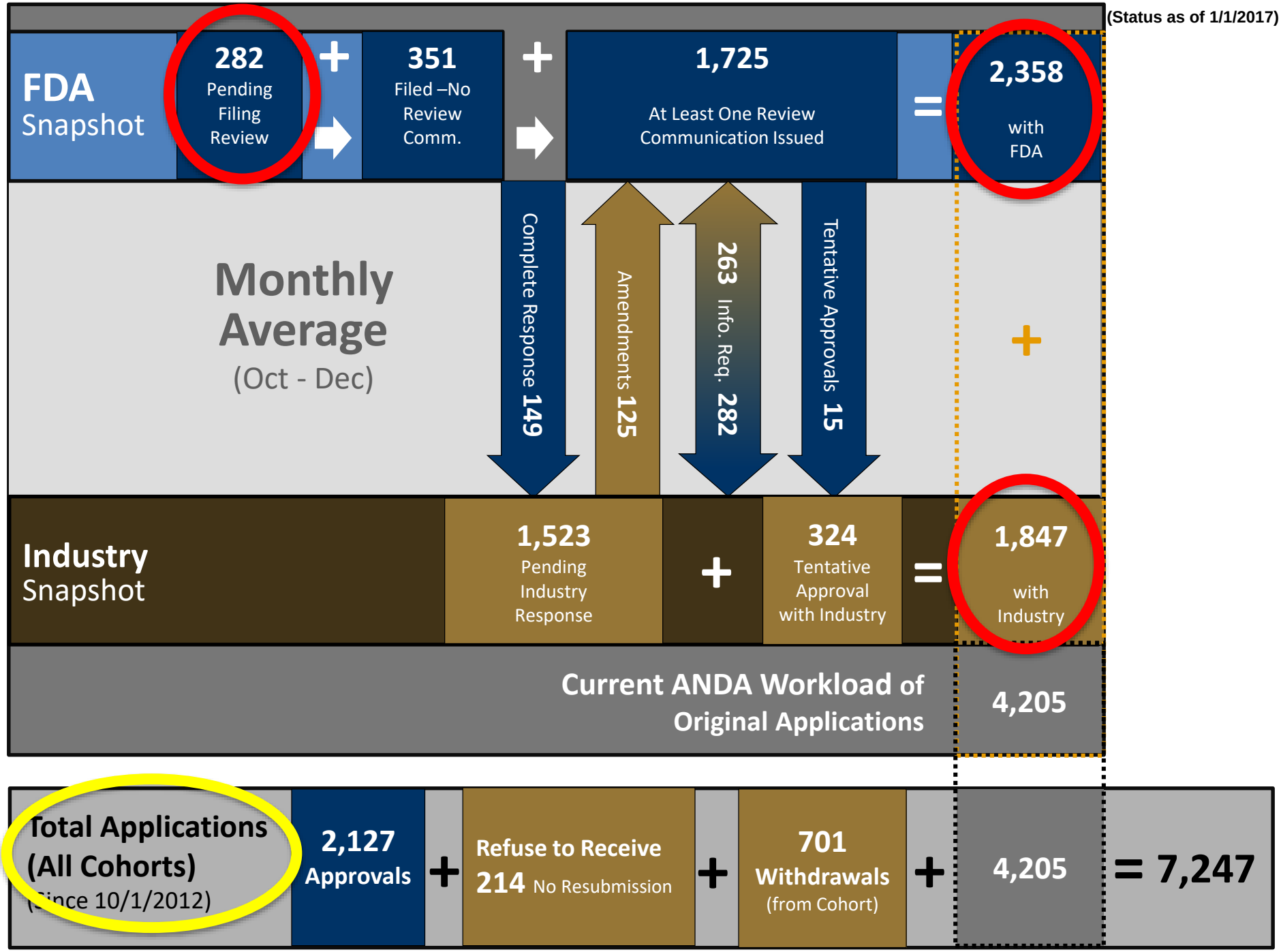
(Status as of 1/1/2017)



(Status as of 1/1/2017)



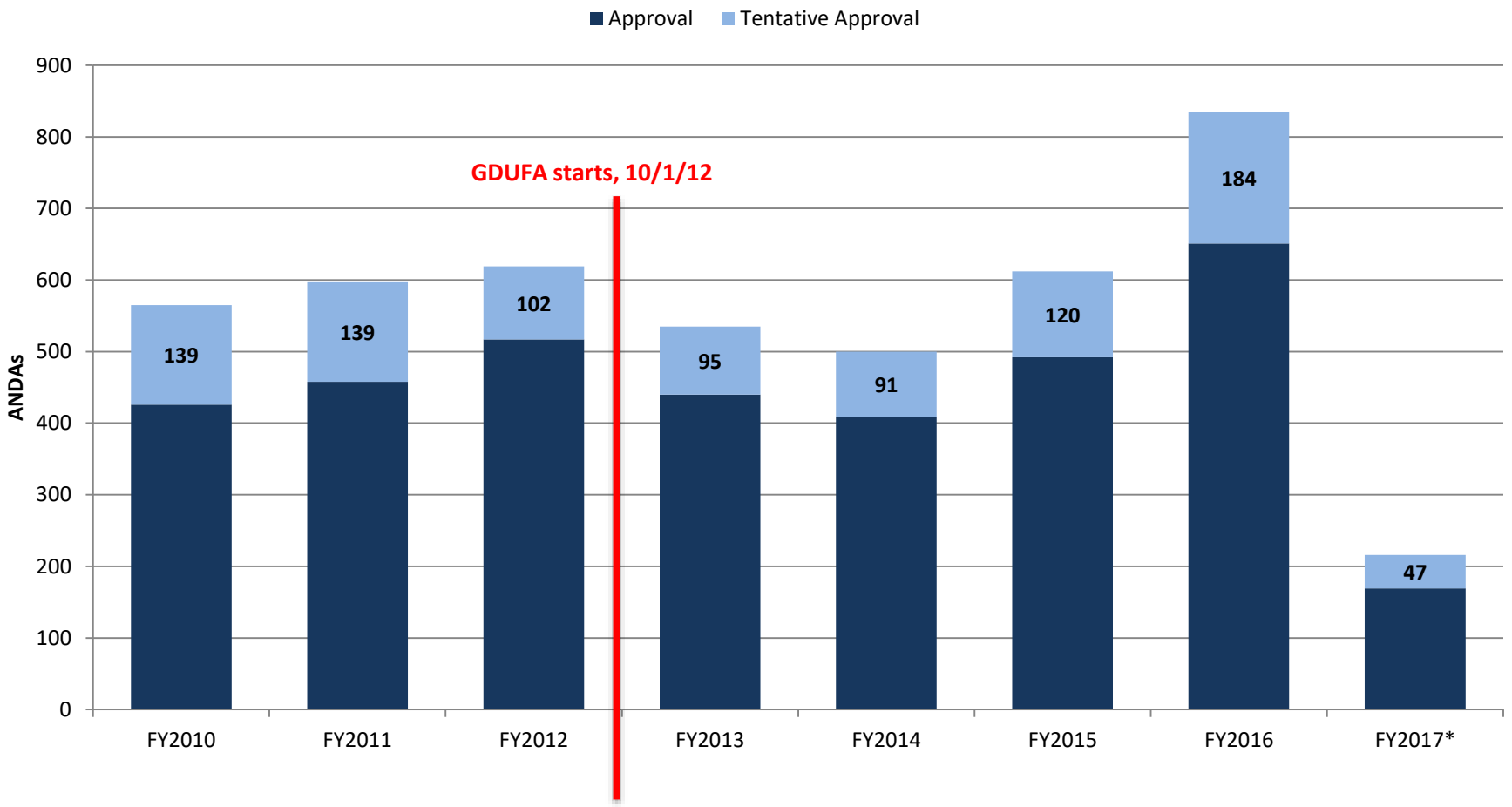
(Status as of 1/1/2017)



Updates – 2.5 Months Later

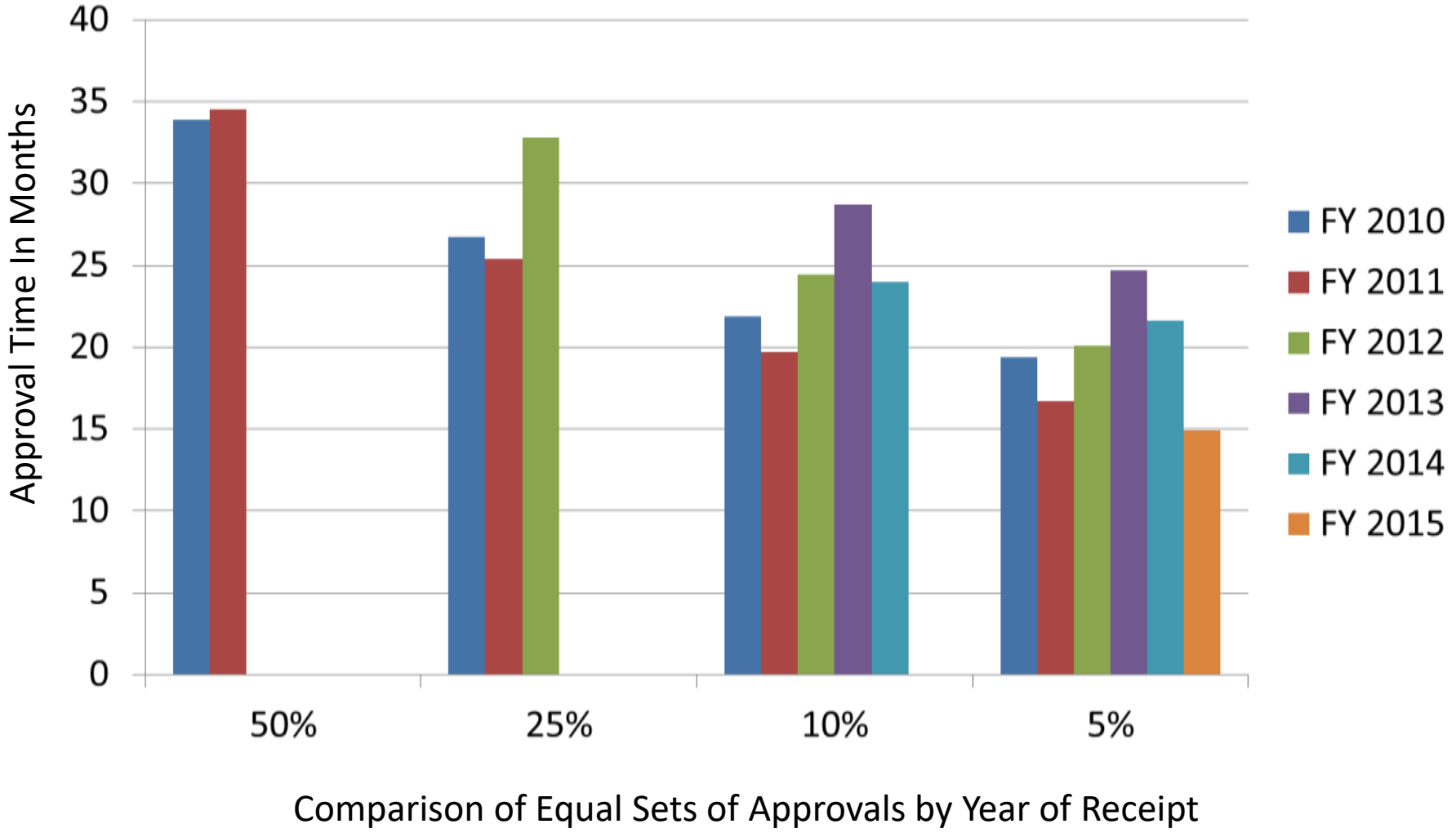
- Pending Filing: 282 *dropped* to 102
- With FDA: 2,358 *dropped* to 2,269
- Approvals: 2,127 *increased* to 2,264

Other Accomplishments: Approvals and Tentative Approvals

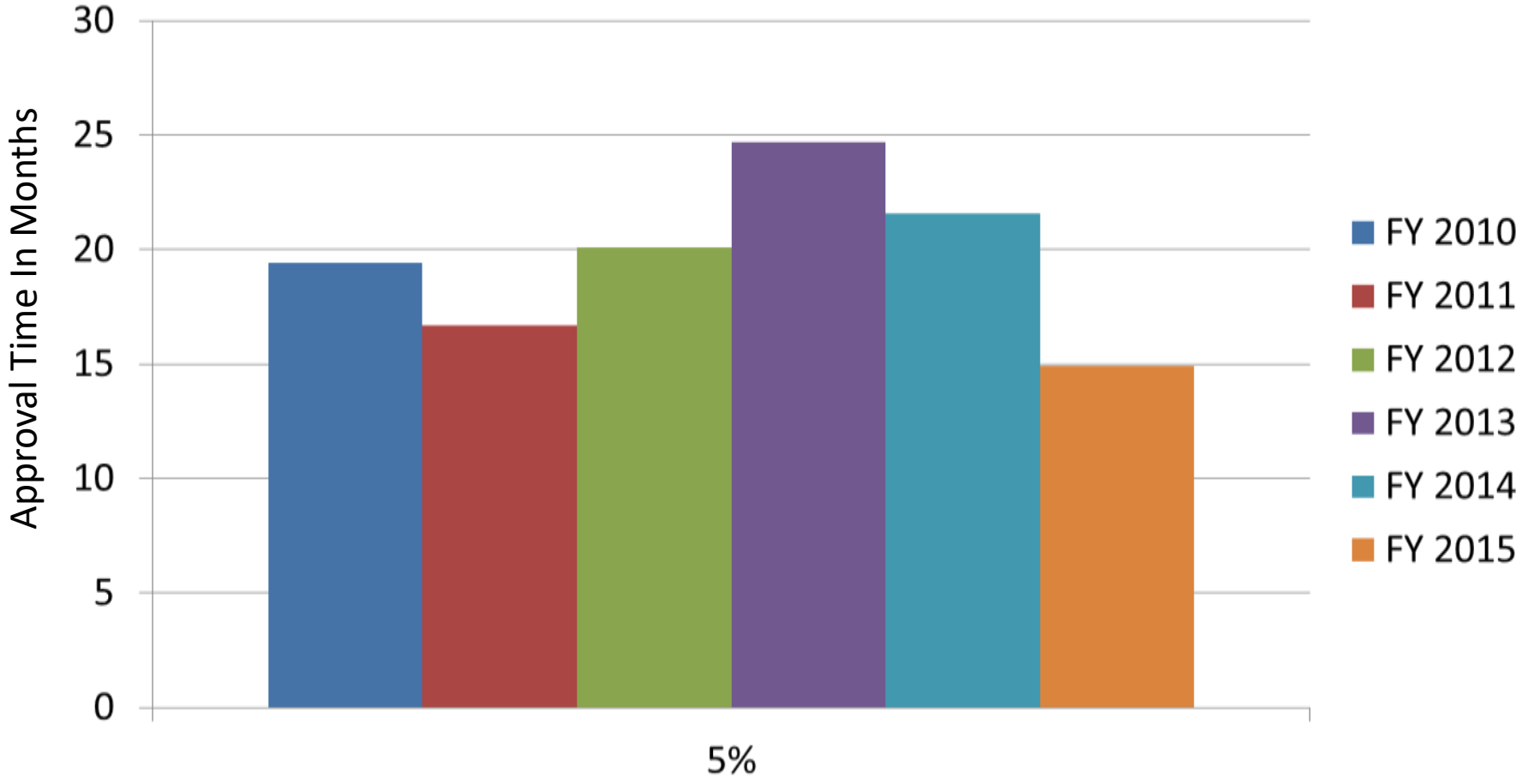


*As of 1/1/17. Numbers are based on preliminary data that will be reviewed and validated for official reporting purposes.

ANDA Median Approval Time: Cohort of Receipt



ANDA Median Approval Time: Cohort of Receipt



Comparison of Equal Set of Approvals by Year of Receipt

Other Accomplishments: Starting to See First Cycle Approvals

First Cycle AP/TA Rate	**9%**
First Cycle CR Rate	**91%**

N=523

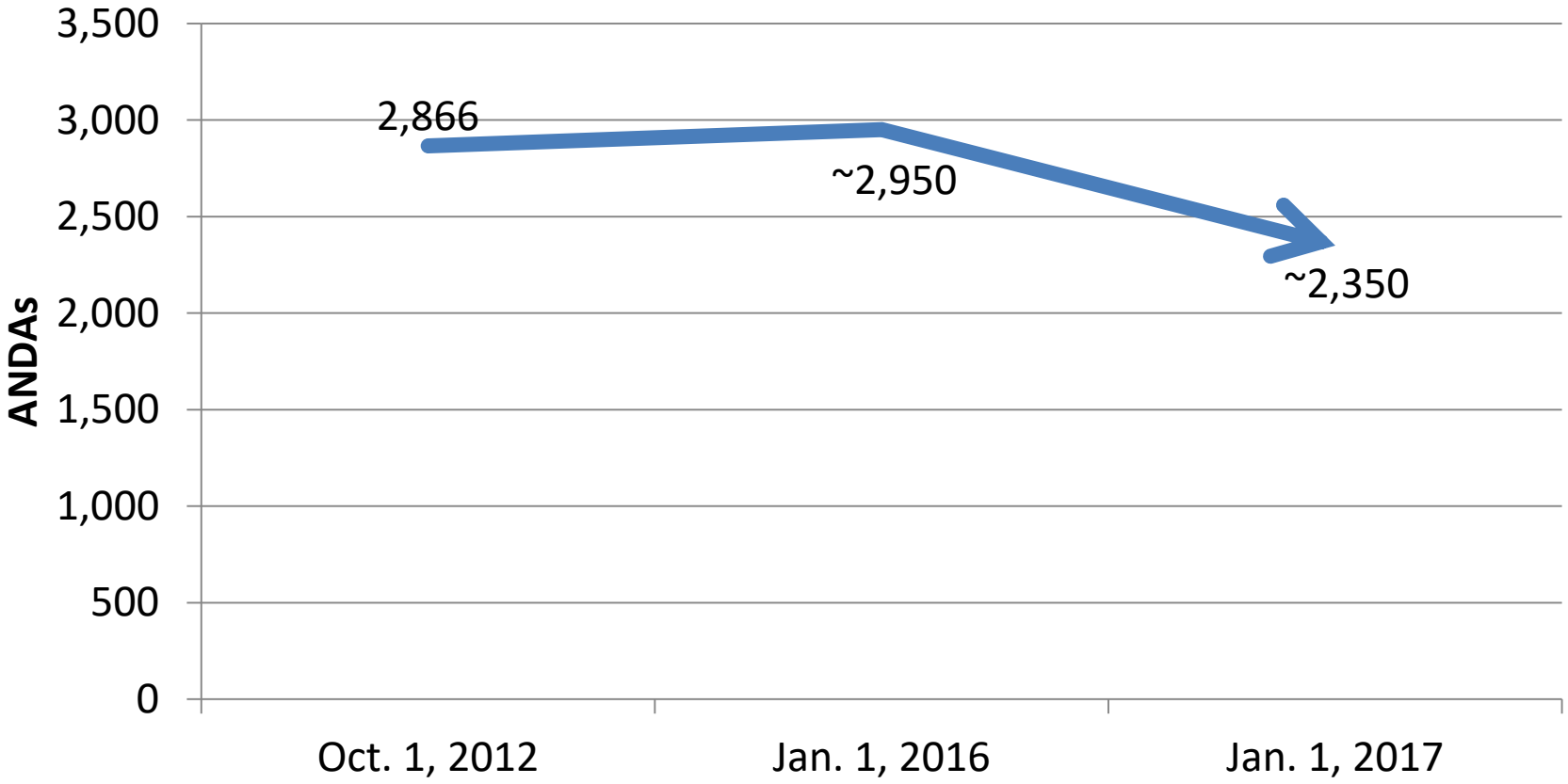
Second Cycles Improving Too

Second Cycle AP/TA Rate	**42%**
Second Cycle CR Rate	**56%**
Withdrawn	**2%**

N=67**

*As of 1/23/17. Numbers are based on preliminary data that will be reviewed and validated for official reporting purposes.
**Completed reviews of second submissions; most others are pending with industry or under review.

ANDAs with FDA

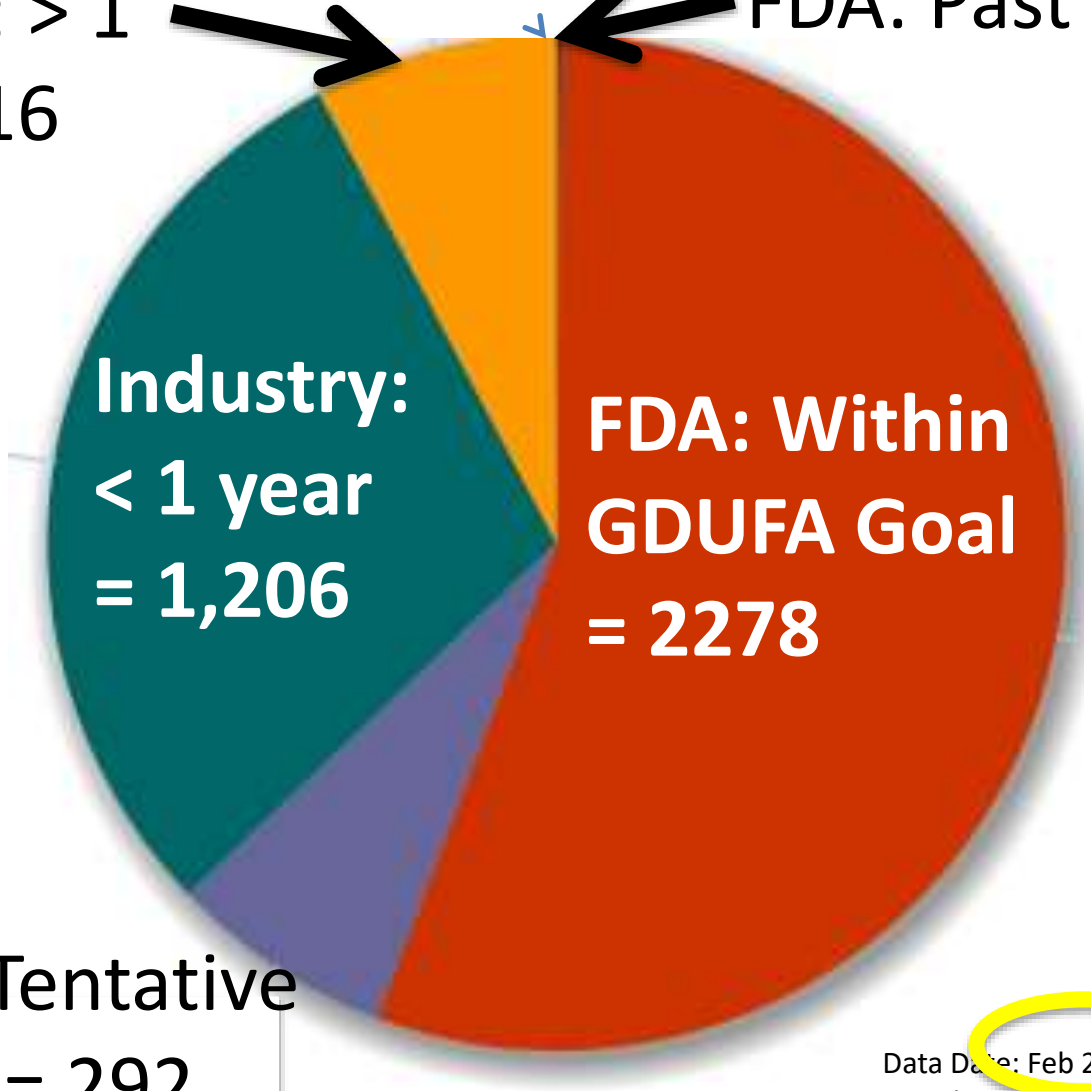


*Approximate Values, January 2017

Unapproved Original ANDAs

Industry: > 1 year = 316

FDA: Past Goal = 6



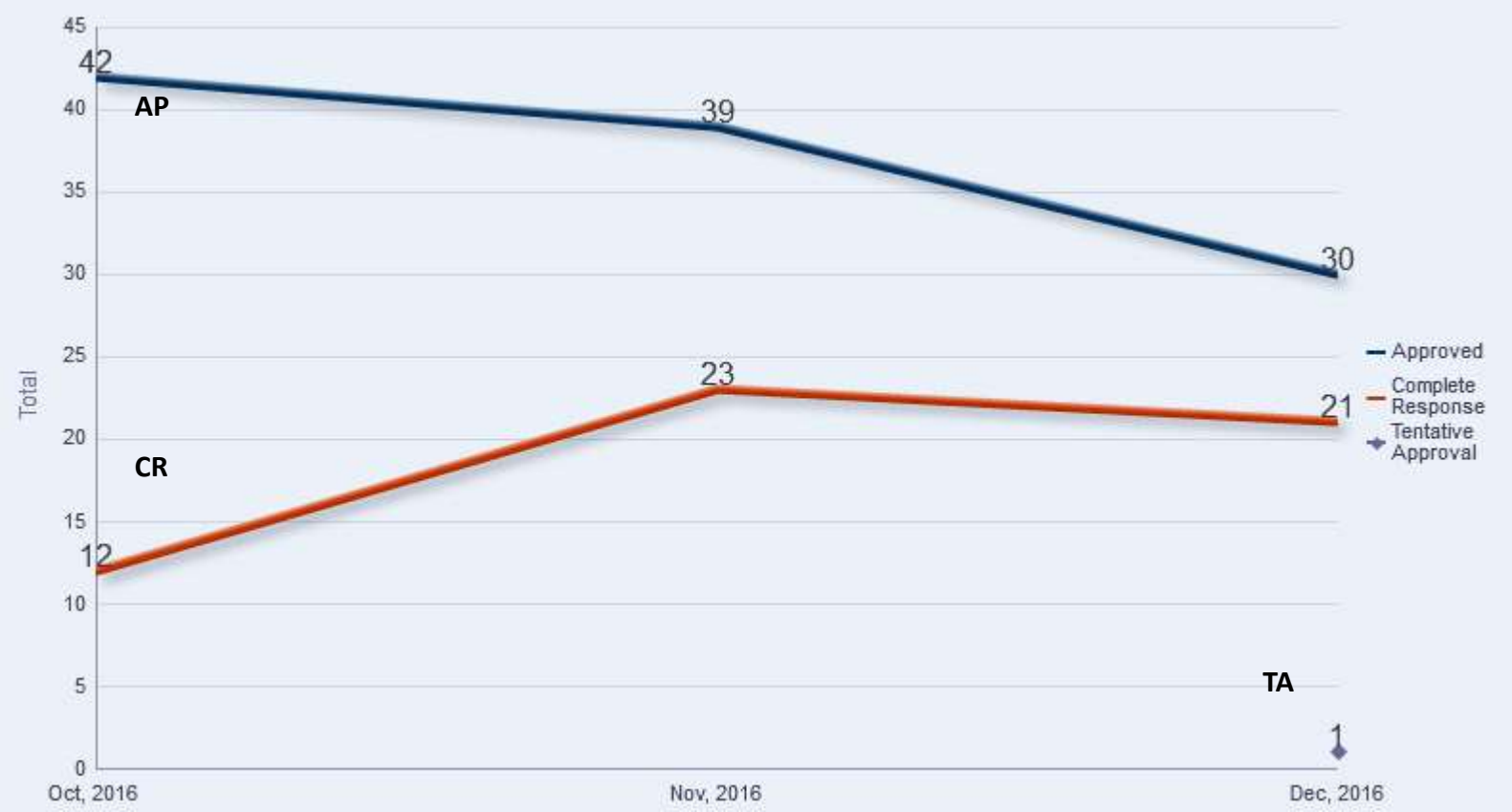
Industry: Tentative Approval = 292

Data Date: Feb 2017
Based on GDUFA I Goals
Caveat: not the same data pull as other slides.

Agenda

- Pre-submission
- Originals
- **Prior-Approval Supplements (PAS)**
- GDUFA II

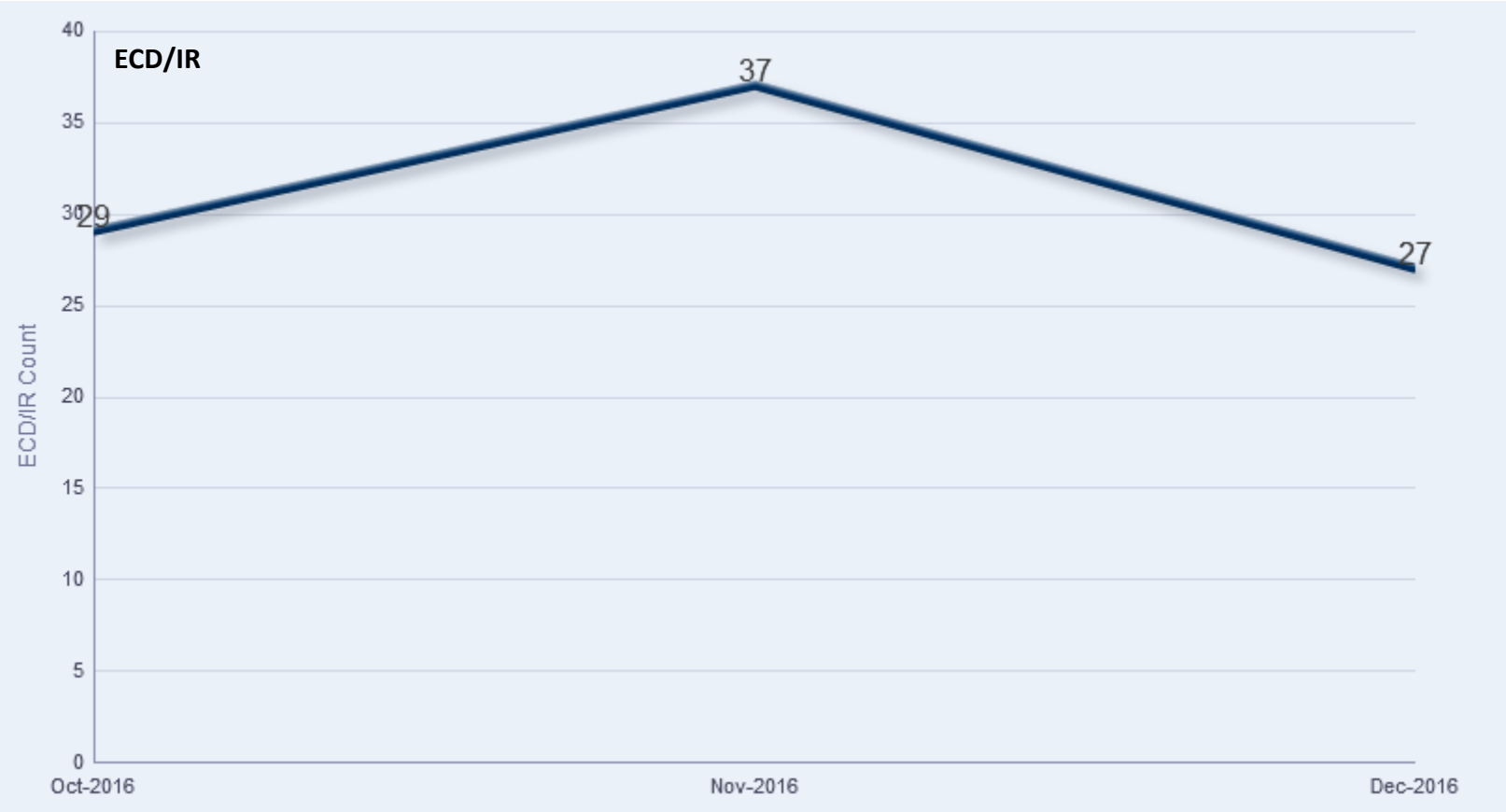
FY16 Trends (ANDA PAS) – Actions Taken by Month (Totals)



Submission Status	Oct, 2016	Nov, 2016	Dec, 2016	Grand Total
Approved	42	39	30	**111**
Complete Response	12	23	21	**56**
Tentative Approval	0	0	1	**1**

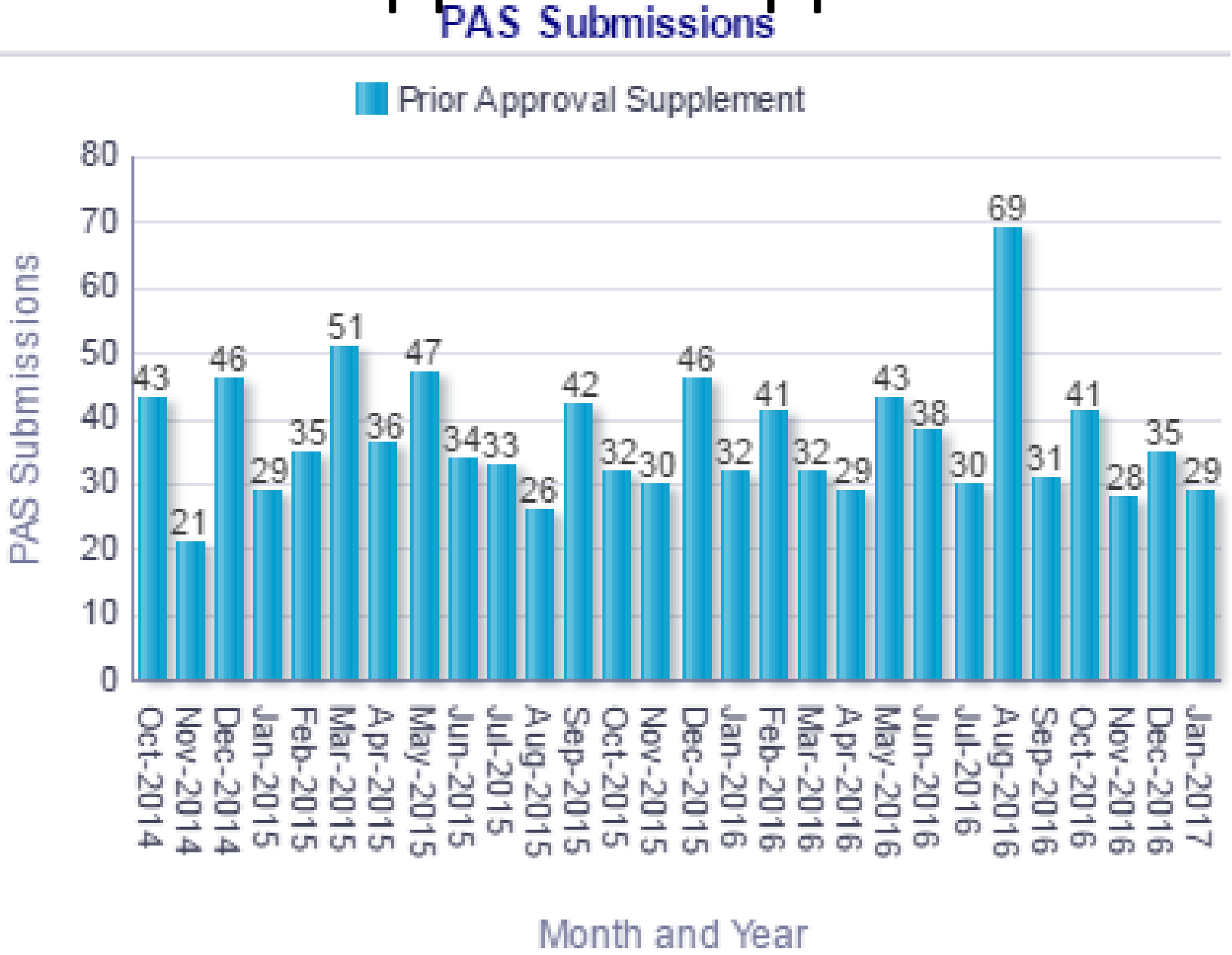
FY16 Trends (ANDA PAS) – ECD/IRs Issued by Month

*excludes filing

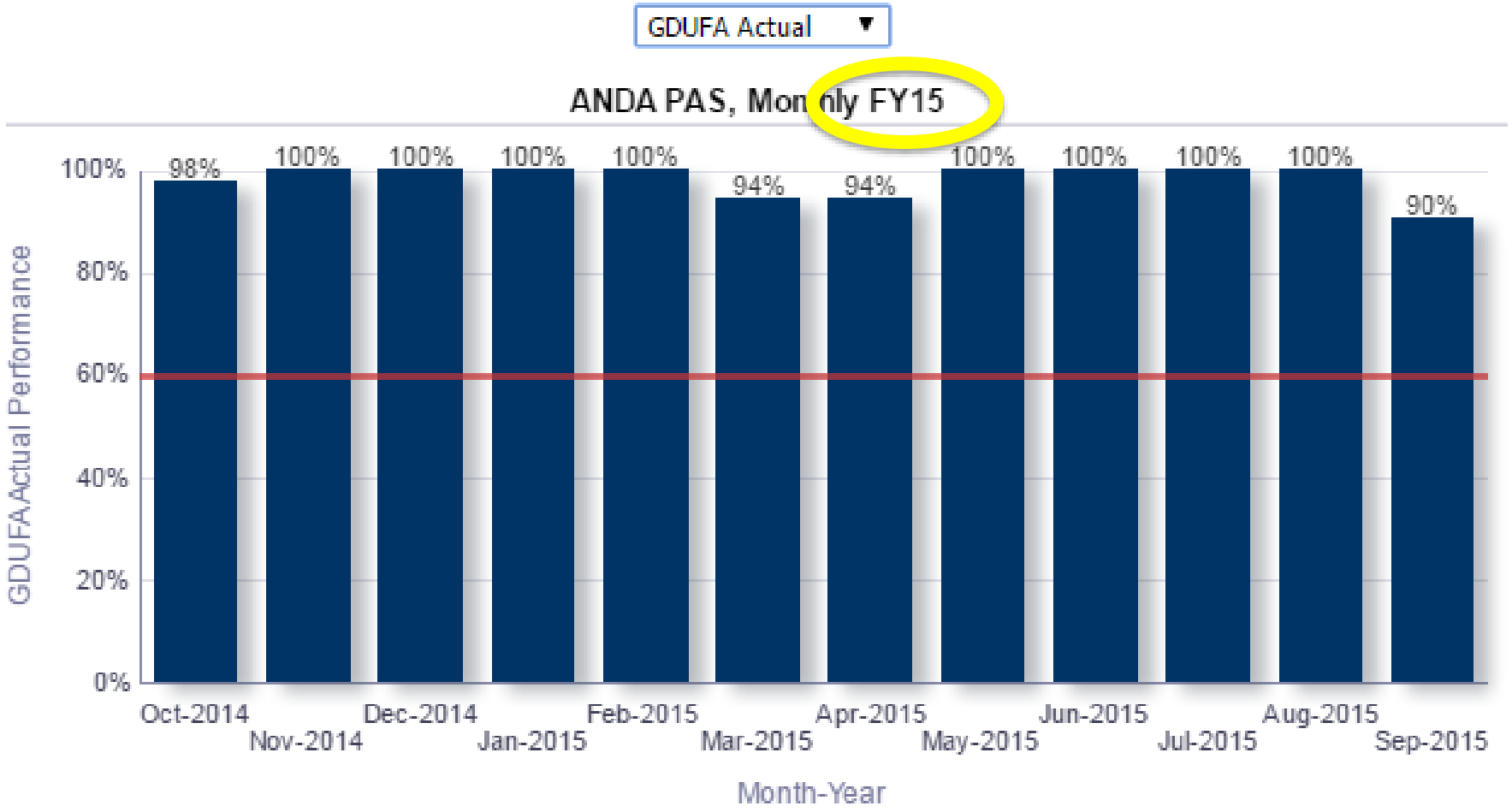


	Oct-2016	Nov-2016	Dec-2016
ECD/IR Count	29	37	27

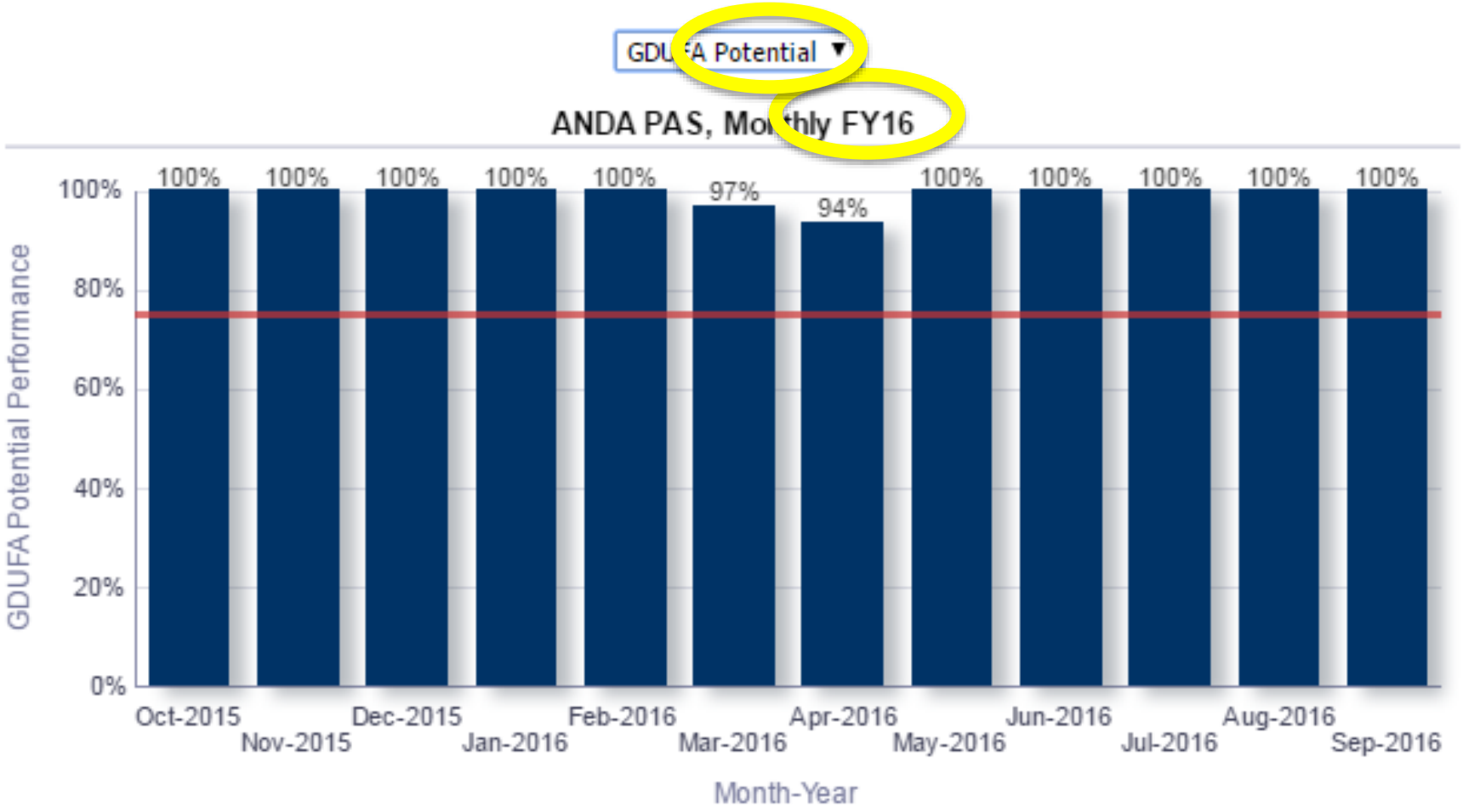
Prior-Approval Supplements



Prior-Approval Supplements: FY 15



Prior-Approval Supplements: FY 16



Concluding Remarks

- The ANDA program is in great shape!
  - Record number of Approvals/Tentative Approvals
  - Thousands of communications
  - Exceeding goals (including GDUFA “backlog” goal)
  - Fewer original ANDAs with FDA
  - Promising future
- It is a good time to submit an ANDA!

Agenda

- Pre-submission
- Originals
- Prior-Approval Supplements (PAS)
- **GDUFA II**

GDUFA II Public Meeting

October 21, 2016

Submission Review Performance Goals Metric

90% FOR ALL

A. Originals (& Amendments)

Submission Type	Goal
Standard Original	10 months (as is)
Priority Original	**8 months w/PFC (NEW)**

PFC = Pre-Submission Facility Communication – complete (all) facilities data package submitted ≥2 months pre-ANDA submission

A. (Orig. &) Amendments (cont.)

Submission Type	Goal
Standard Major	10 months w/inspection 8 months no inspection
Priority Major	10 months w/insp. no PFC 8 months w/insp. w/PFC 6 months no inspection

A. (Orig. &) Amendments (cont.)

Submission Type	Goal
Standard Minor	3 months
Priority Minor	3 months

B. PAS (& PAS Amendments)

Submission Type	Goal
Standard PAS	10 months w/inspection 6 months no inspection
Priority PAS	10 months w/insp. no PFC **8 months w/insp. w/PFC** **4 months no inspection**

B. (PAS &) PAS Amend. (cont.)

Submission Type	Goal
Standard Major	10 months w/inspection 6 months no inspection
Priority Major	10 months w/insp. no PFC **8 months w/insp. w/PFC** **4 months no inspection**

B. (PAS &) PAS Amend. (cont.)

Submission Type	Goal
Standard Minor	3 months
Priority Minor	3 months

F. GDUFA I "Bridging"

1. GDUFA I Goal Applications – honor existing goals
2. Backlog and GDUFA I non-Goal Applications – honor existing TADs
3. Missed or missing goals – NLT July 31, 2018
4. ***All*** new subs/amendments – GDUFA II

FDA U.S. FOOD & DRUG ADMINISTRATION

Questions?

Please complete the session survey:

surveymonkey.com/r/GDF-D1S04

Thank you!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