ANDA Performance/ Operations Update

Ted Sherwood
Director
Office of Regulatory Operations
Office of Generic Drug
CDER/FDA

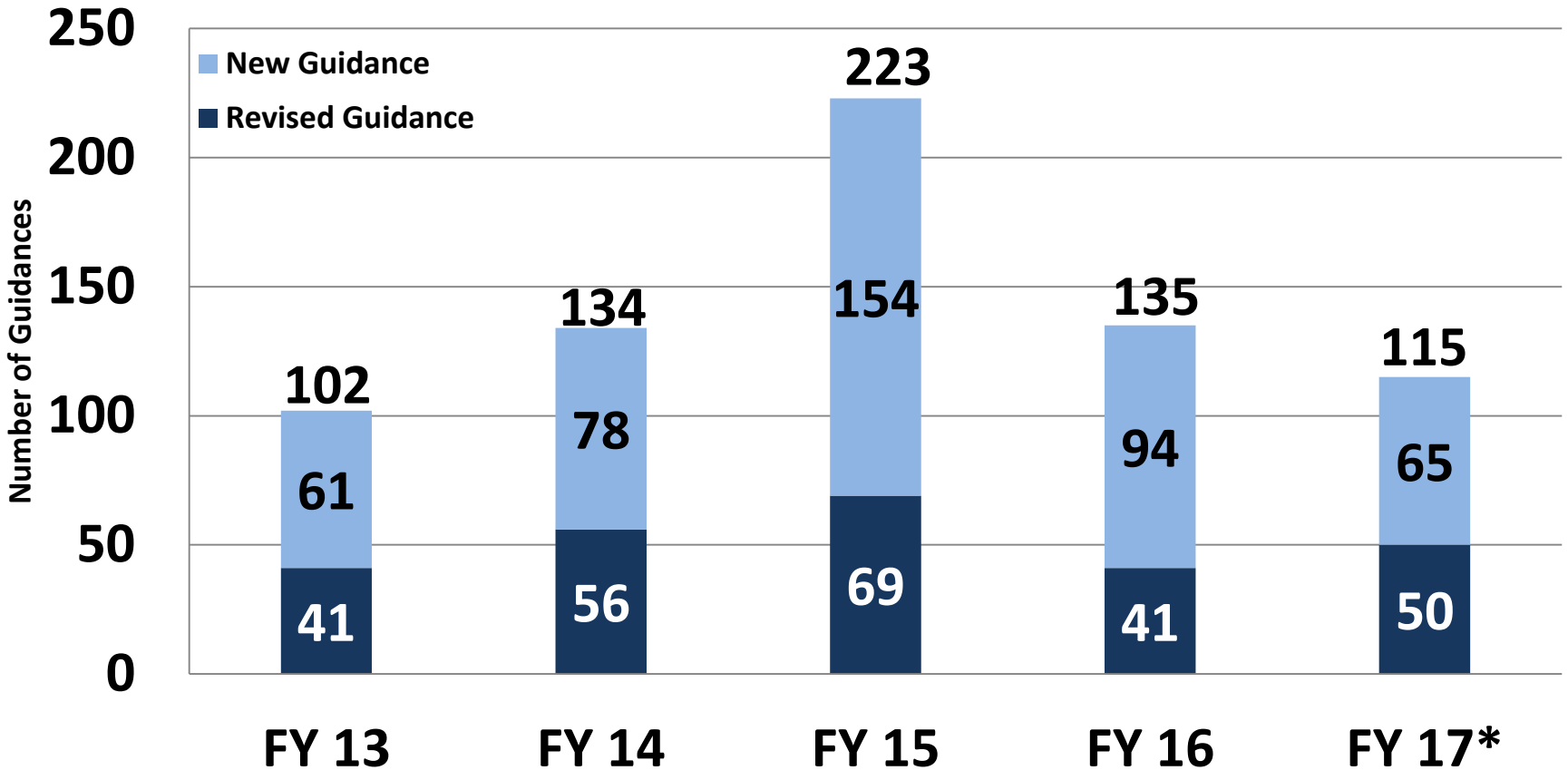
CDER Small Business and Industry Assistance (SBIA) Regulatory Education for Industry (REdI): Generic Drugs
April 11, 2018

How is the ANDA program doing and what is the real story behind the GDUFA II performance?

Agenda

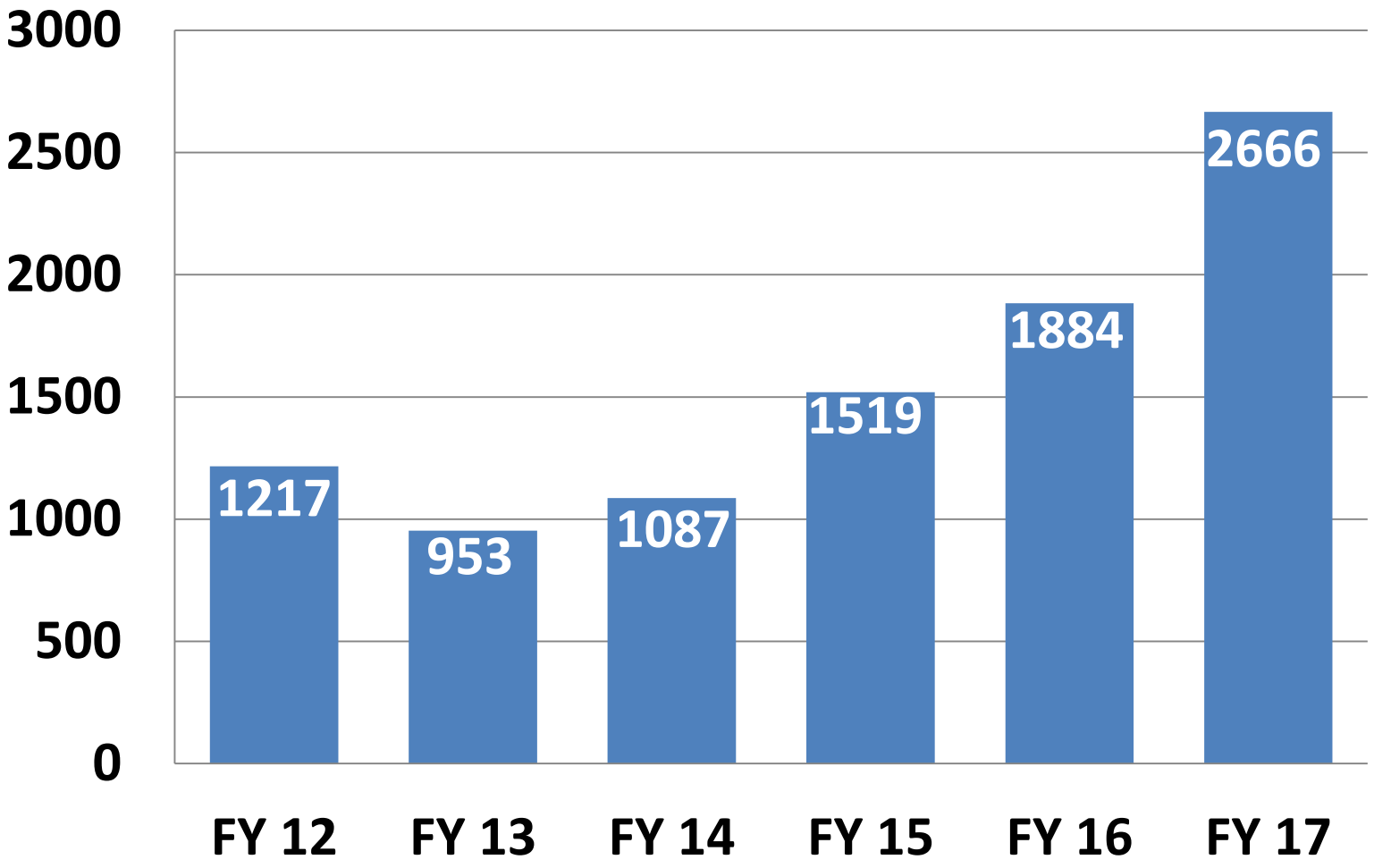
- Pre-submission
- Originals
- Prior Approval Supplements (PASs)
- Metrics

Product-Specific Guidances



* Set of guidances expected at the end of FY 17 were released in early FY 18

Controlled Correspondence Received



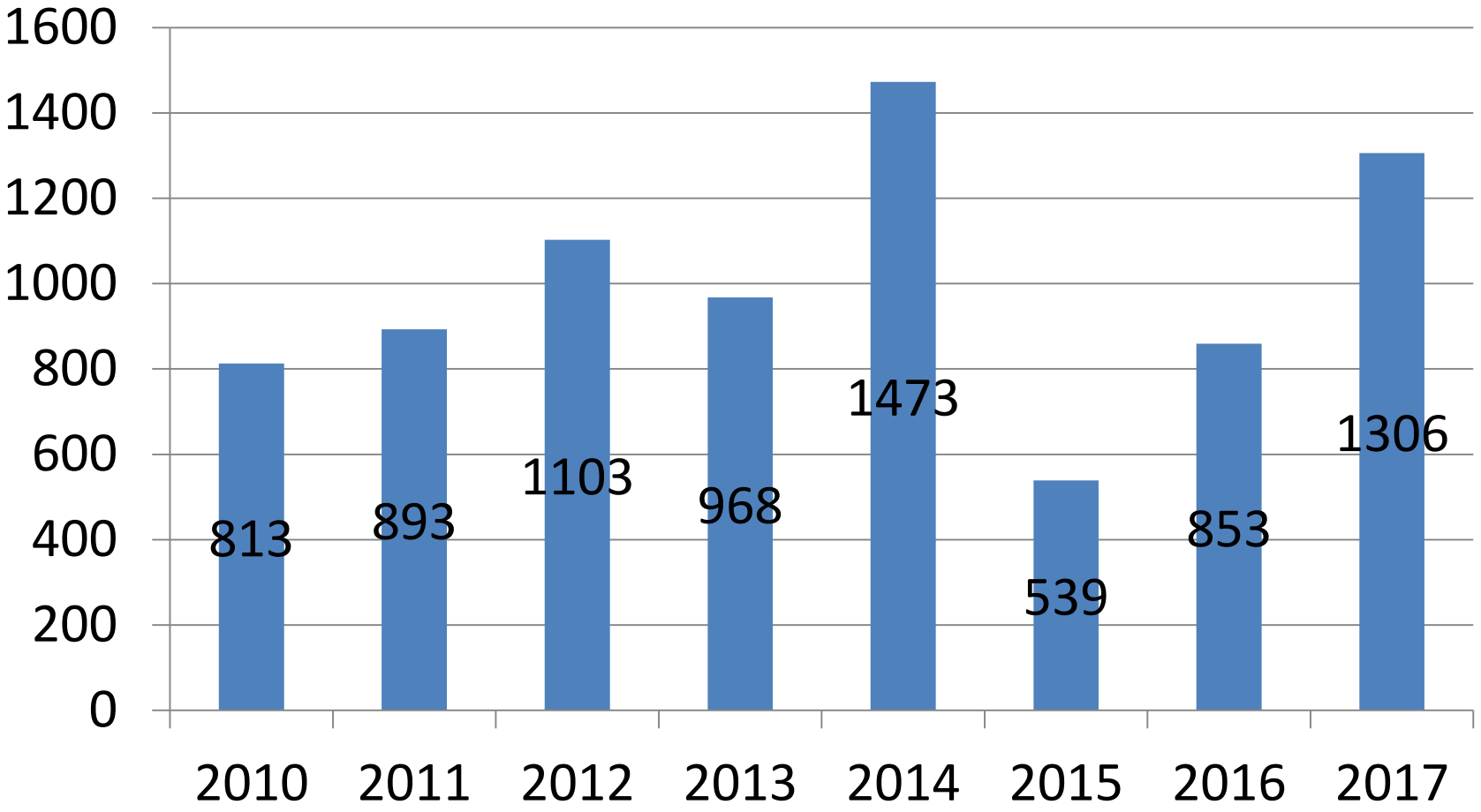
Controlled Correspondence & GDUFA II

- Goals:
  - Standard: 90% within 60 days
  - Complex: 90% within 120 days
    - Involving evaluation of clinical content
    - BE protocols for RLDs with REMS ETASU
    - Evaluation of alternate BE approaches within same study type
- Performance: Exceeding the 90% goals

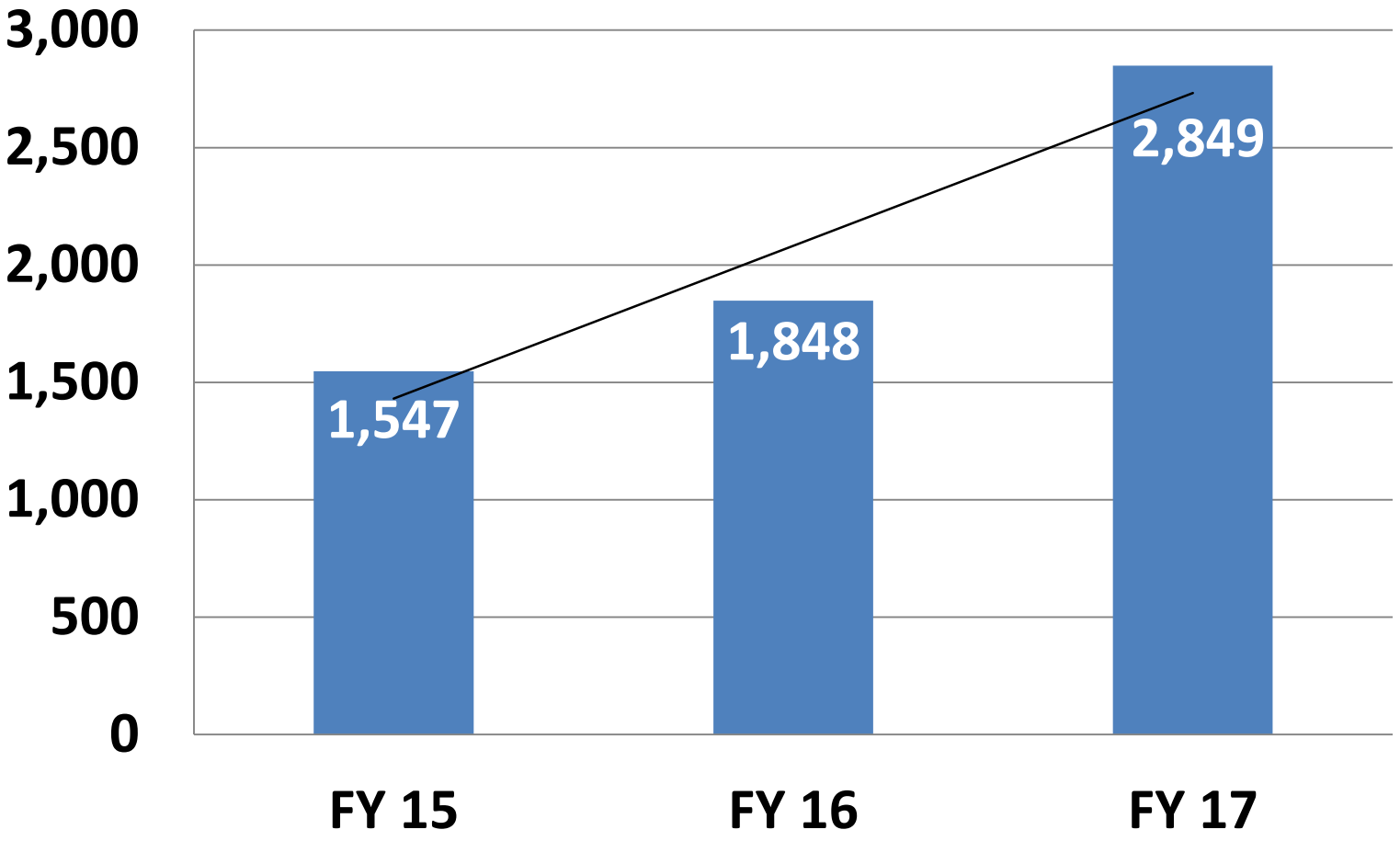
Agenda

- Pre-submission
- Originals
- Prior Approval Supplements (PASs)
- Metrics

ANDA Receipts (Originals)



ANDA Receipts Originals & CR Responses/Amendments



* Updated 10/1/2017. Numbers are based on preliminary data that will be reviewed and validated for official reporting purposes.

Refuse to Receive (RTR)

	% ANDAs RTR-ed*
FY2015 (cohort Year 3)	34.3
FY2016 (cohort Year 4)	28.3
FY2017 (cohort Year 5)	10.5
Overall RTR % FY15-17	**20.9**

MAPP 5220.3 should help keep RTR rates low (Communicating Certain Deficiencies Identified During Filing Review of ANDAs)

Impact of RTRs

- Not desired state – don't make us RTR
  - Pressure to follow regulations, etc.
  - Pressure to be consistent - no breaks allowed including:
    - Company size or experience
    - Administrative or inadvertent errors

Impact of RTRs (cont.)

- No value to FDA in RTRs
  - Additional resources required to issue RTRs
  - Frequent Requests For Reconsideration and Formal Dispute Resolution Requests – very resource intensive
- Potential to delay Approval/Tentative Approval
  - FDA wants approvals each month
  - FDA needs approvals for drug shortage, DCAP, 1st generics, etc.

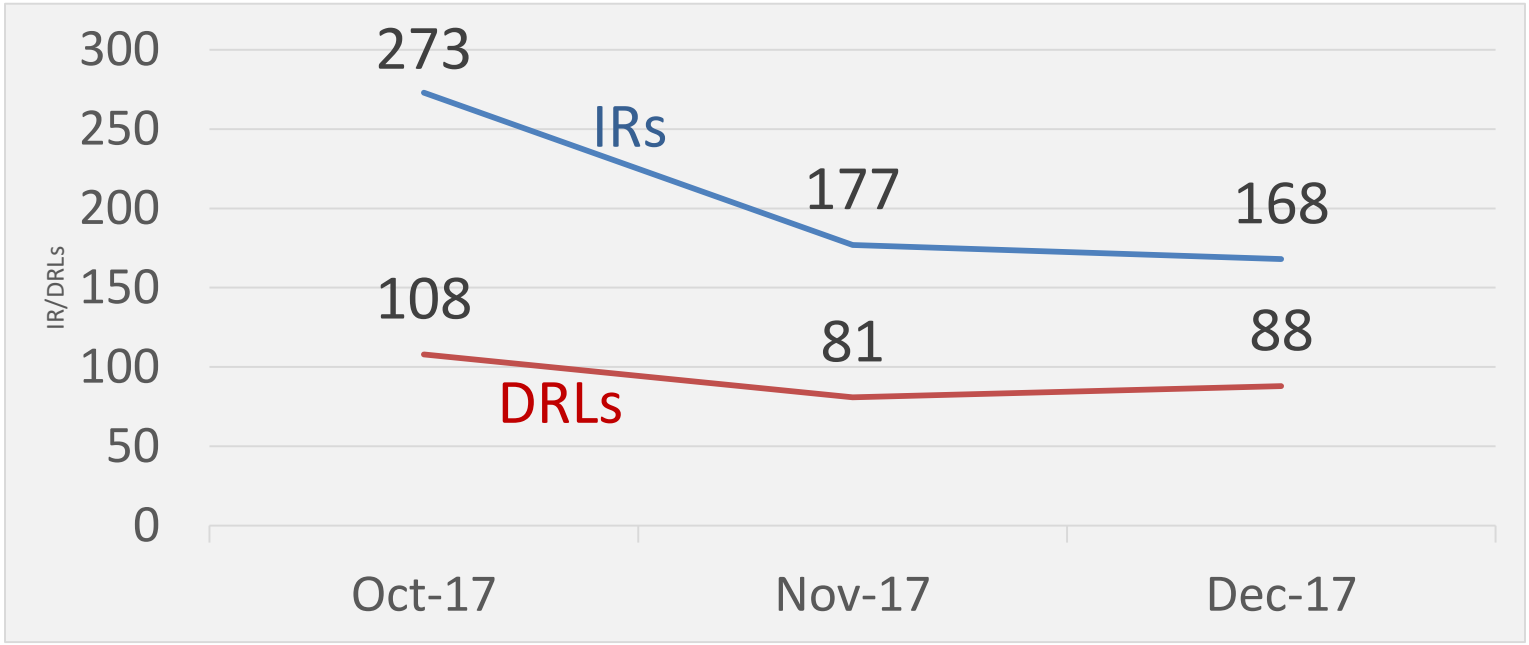
Tip - Invest in a Quality Application!

- Saves you time
- Saves you money
  - Filling fees
  - Delayed market entry
- Saves your assessors' time

Do you want your review team searching for data or making an assessment?

What message are you sending the review team with a sloppy application?

FY18 Trends (ANDA Originals) – IR/DRLs Issued by Month



*excludes filing

IRs – Information Requests
DRLs – Discipline Review Letters

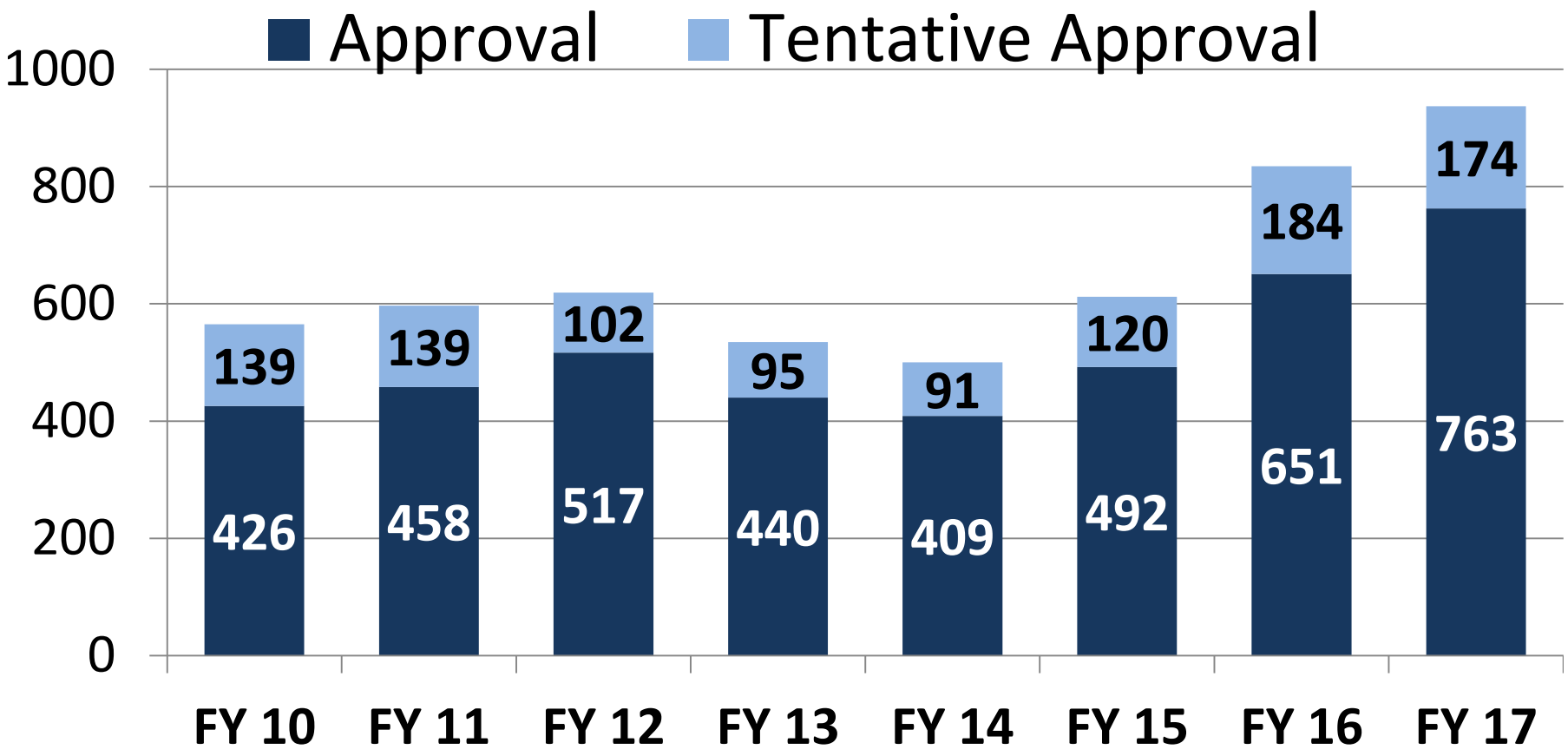
Tip – Response Should Be

- Complete
- Accurate
- Consistent with the “story” of your ANDA
- On time

Use these communications to close out the cycle with an Approval!

FY18 Trends (ANDA Originals) – Actions Taken by Month (Totals)

Annual Approvals & Tentative Approvals



*Updated 10/1/2017. Numbers are based on preliminary data that will be reviewed and validated for official reporting purposes.

First Cycle Approvals

FY2015	**10.7%**
FY2016	**14.3%**
FY2017	**12.8%**

- Low %, but improving w/ DRLs
- Great way to pull ahead of the competition

How Serious Does FDA Treat the Goals?

- Very!
- Reporting built into GDUFA II program
- Annual reporting to Congress – explanations for misses
- The Government Accountability Office (GAO) – expected to audit

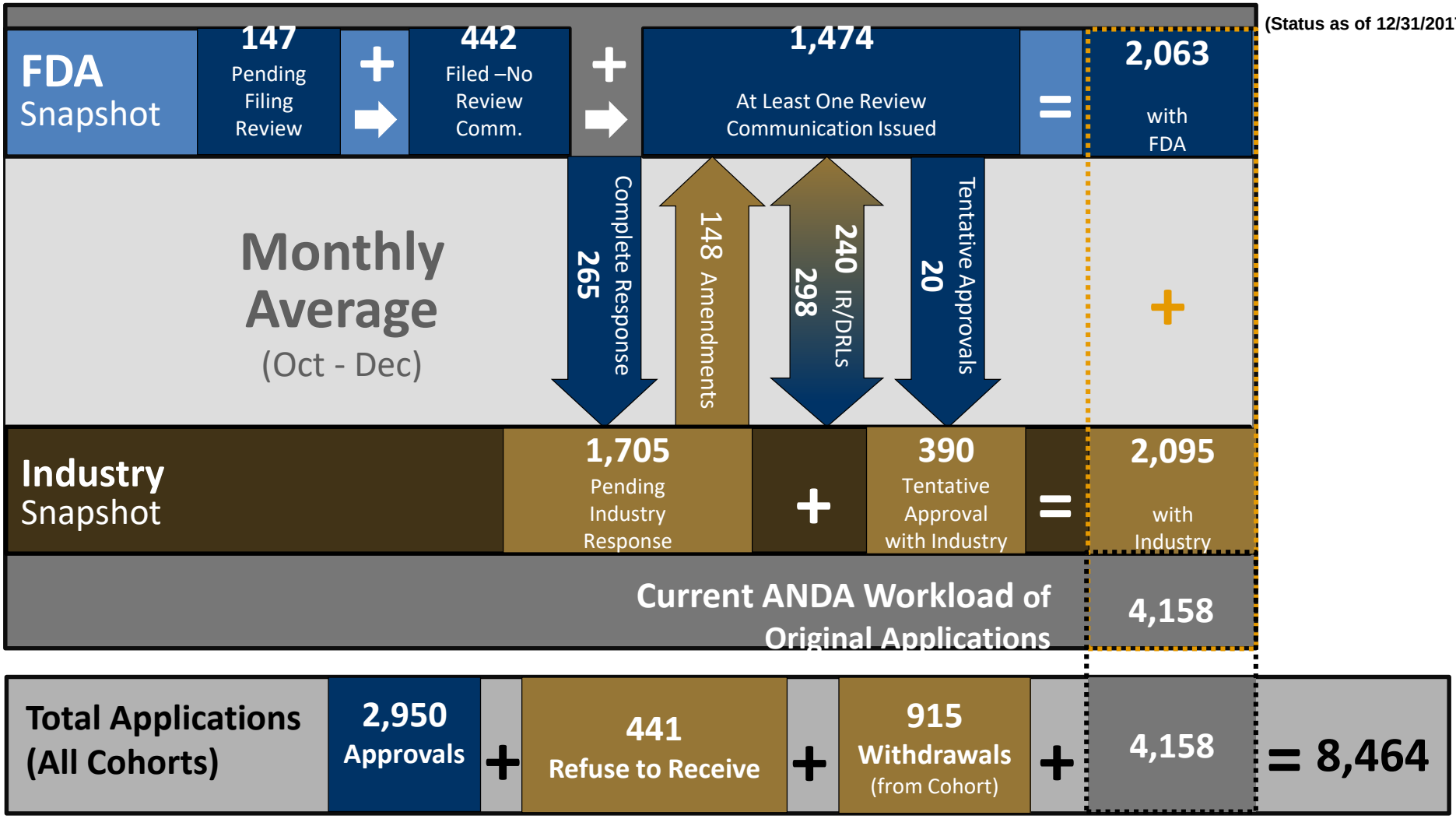
GDUFA II Month XX Misses Report

1	Status	Effective Date	Make or Miss	Reason for the Miss.
2	Complete Response	~2.5 weeks	missed	ODD Missed - XXX Review completed xx days after ODD and YYY review completed xx days after ODD
3	Approved	4 days	missed	**Imminent Approval**- misses due to applicant zzzz. IR for zzzz sent to applicant by XXX x/x/xx, applicant replied x/x/xx (IR close to goal date)
4	Complete Response	2 days	missed	Missed ODD- XXX; XXX RVW completed x/x/xx, amended to account for YYYY input]
5	Complete Response	3 days	missed	Missed ODD -XXXX Consult. GDUFA Sat., so we need to take an action on Fri. YYYY had to wait on both a ZZZZ and XXXX consult. The ZZZZ review was completed on x/x/xx . The XXXX consult was completed on x/x/xx.

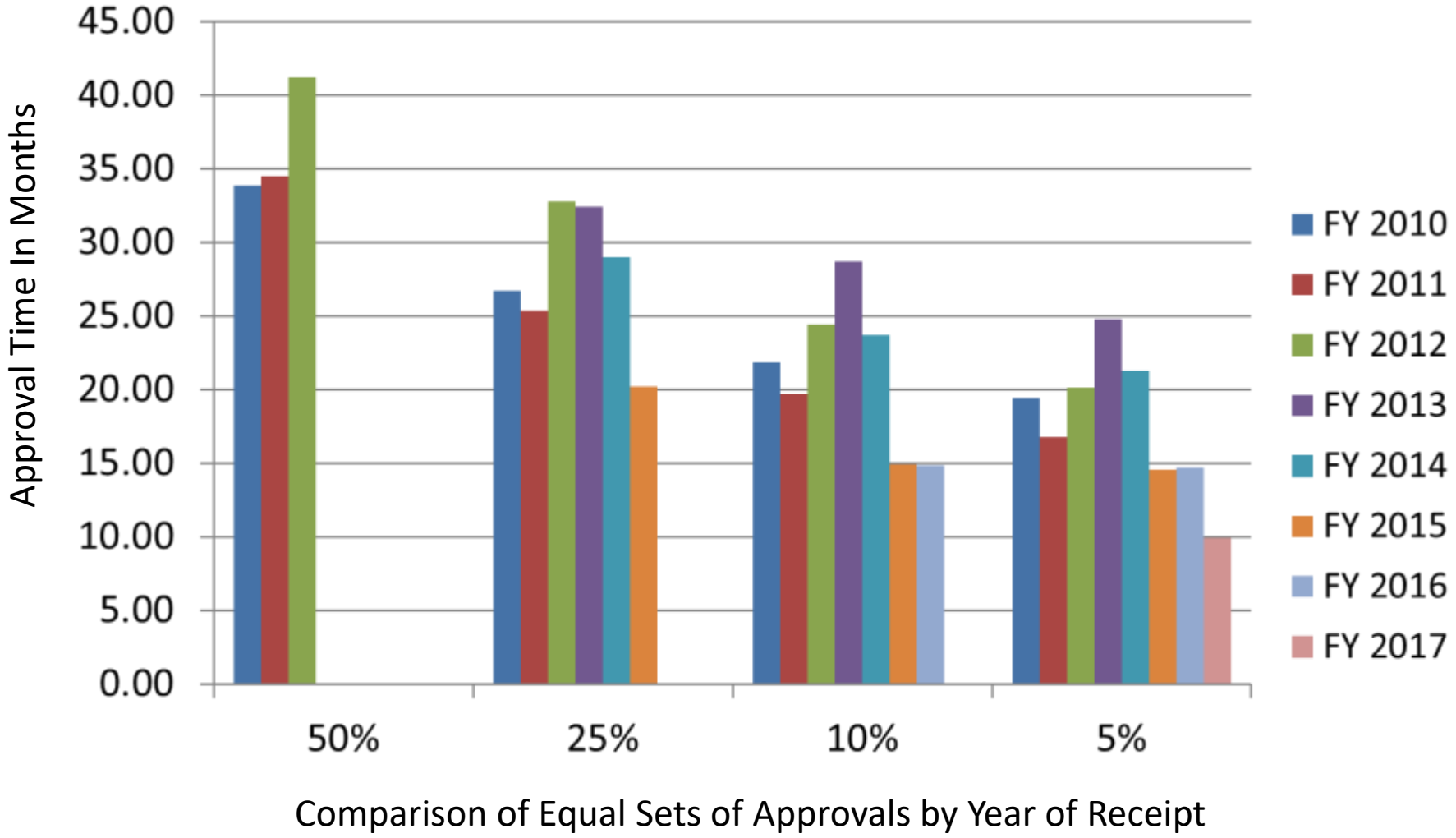
GDUFA II Month XX Misses (cont.)

6	Approved	8 days	missed	Missed ODD - late IRs, XXXX reviews finalized xx days after ODD. (IRs close to goal)
7	Tentative Approval	>30 days	missed	**Imminent TA**. The applicant only had NN zzzzz to address, which was the only thing making XXXX inadequate. The TA letter was signed x/x/xx. (IR close to goal)
8	Pending		pending	**Imminent approval**, applicant to verify that zzzz requirements are met (IR close to goal)
9	Approved	1 day	missed	**Imminent approval.** missed by one day since GDUFA date not in sync with actionable date. **On target for actionable date (x/x/xx)**
10	Pending		pending	**Imminent Approval**. **GDUFA goal date of x/x/xx which is before the date of patent expiry x/x/xx. This is the date the ANDA is eligible for approval.**

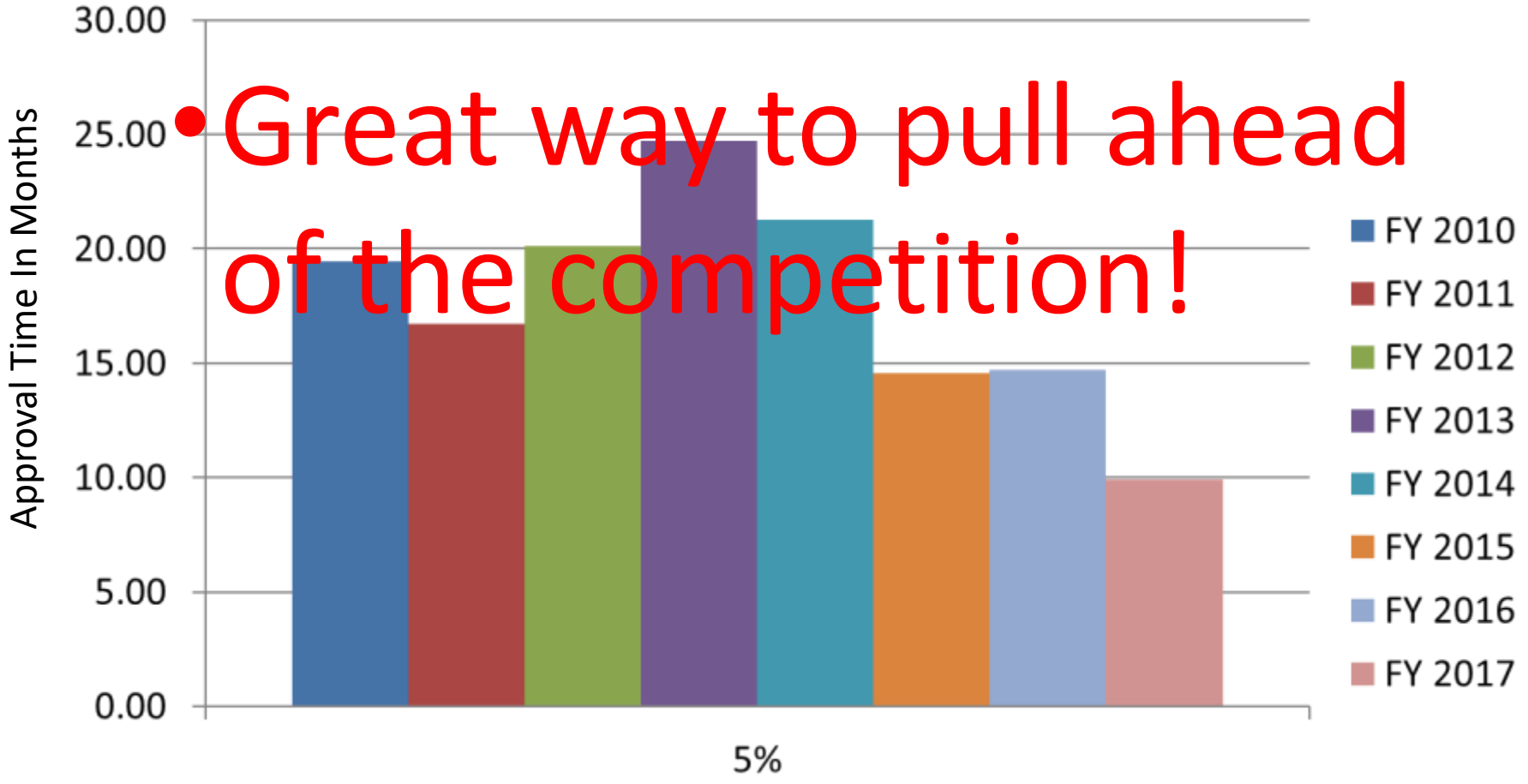
Application Flow by the Numbers



ANDA Median Approval Time: Cohort of Receipt



ANDA Median Approval Time: Cohort of Receipt



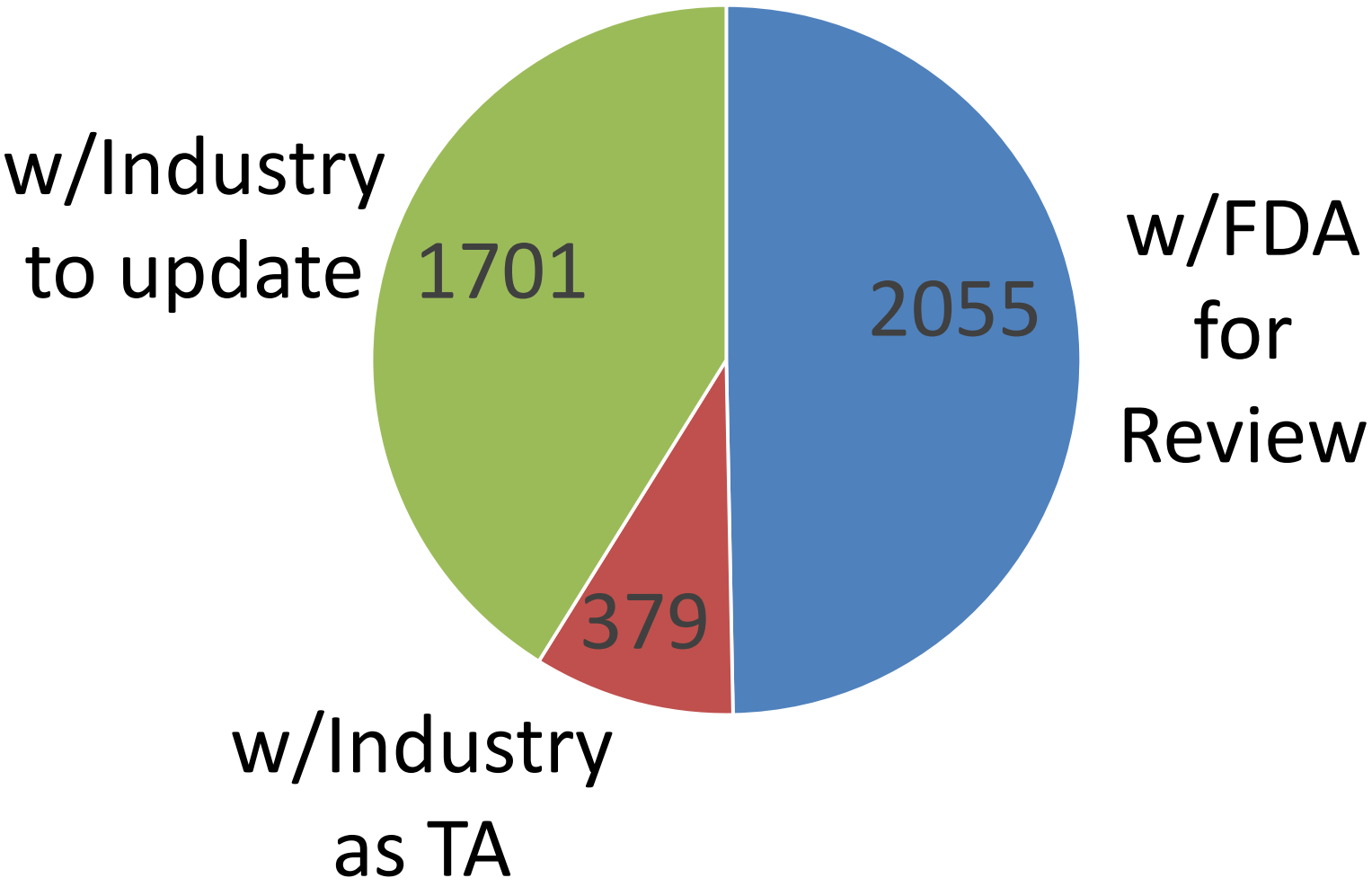
- Great way to pull ahead of the competition!

Comparison of Equal Set of Approvals by Year of Receipt

Median Time to Tentative Approval

29.85 months and dropping!

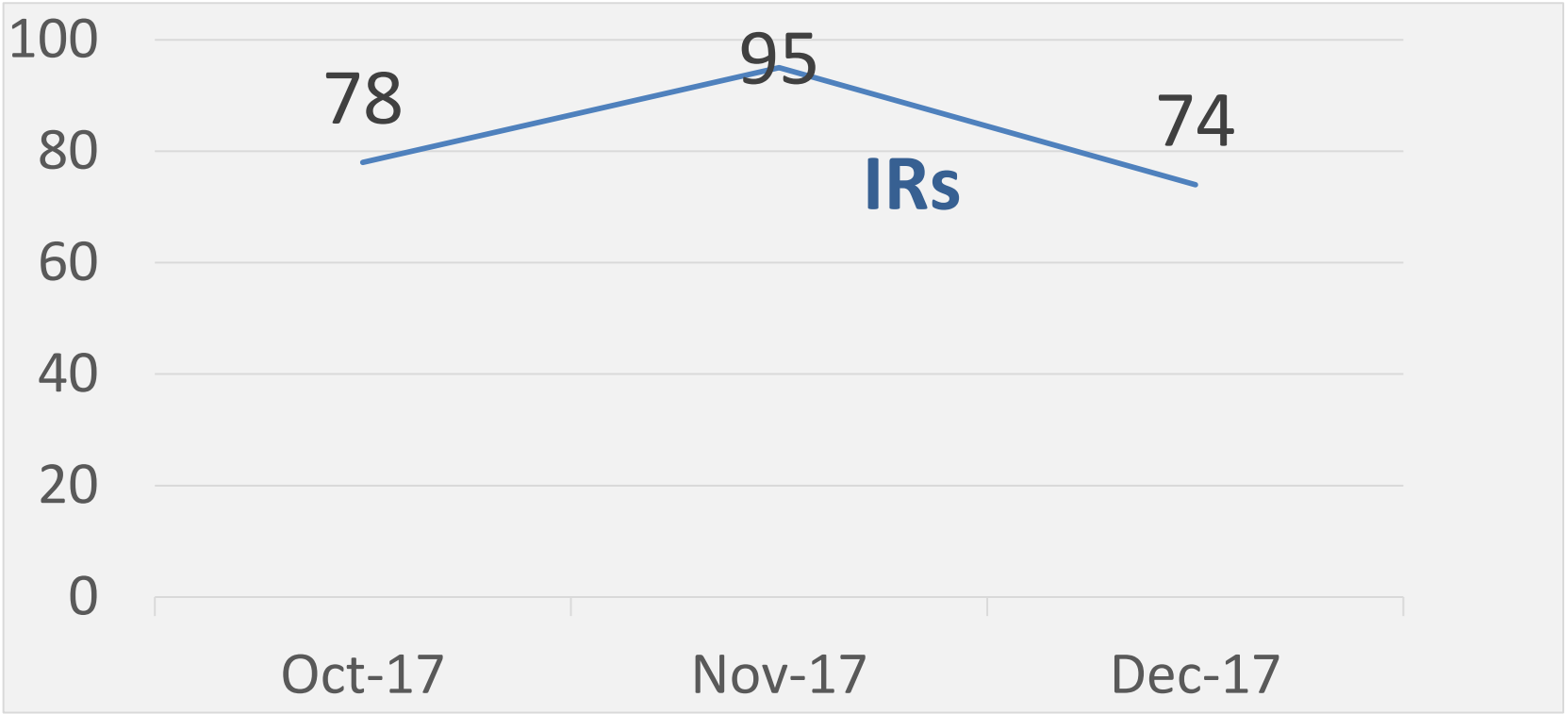
Unapproved Original ANDAs



Agenda

- Pre-submission
- Originals
- Prior Approval Supplements (PASs)
- Metrics

FY18 Trends (ANDA PAS) – IRs Issued by Month



*excludes filing

FY18 Trends (ANDA PAS) – Actions Taken by Month (Totals)

Submission Status	Oct, 2017	Nov, 2017	Dec, 2017	Grand Total
Approved	41	27	35	103
Complete Response	14	12	9	35

Agenda

- Pre-submission
- Originals
- Prior Approval Supplements (PASs)
- *Metrics*

GDUFA Metrics

- > 3200 goals were assigned in four months!

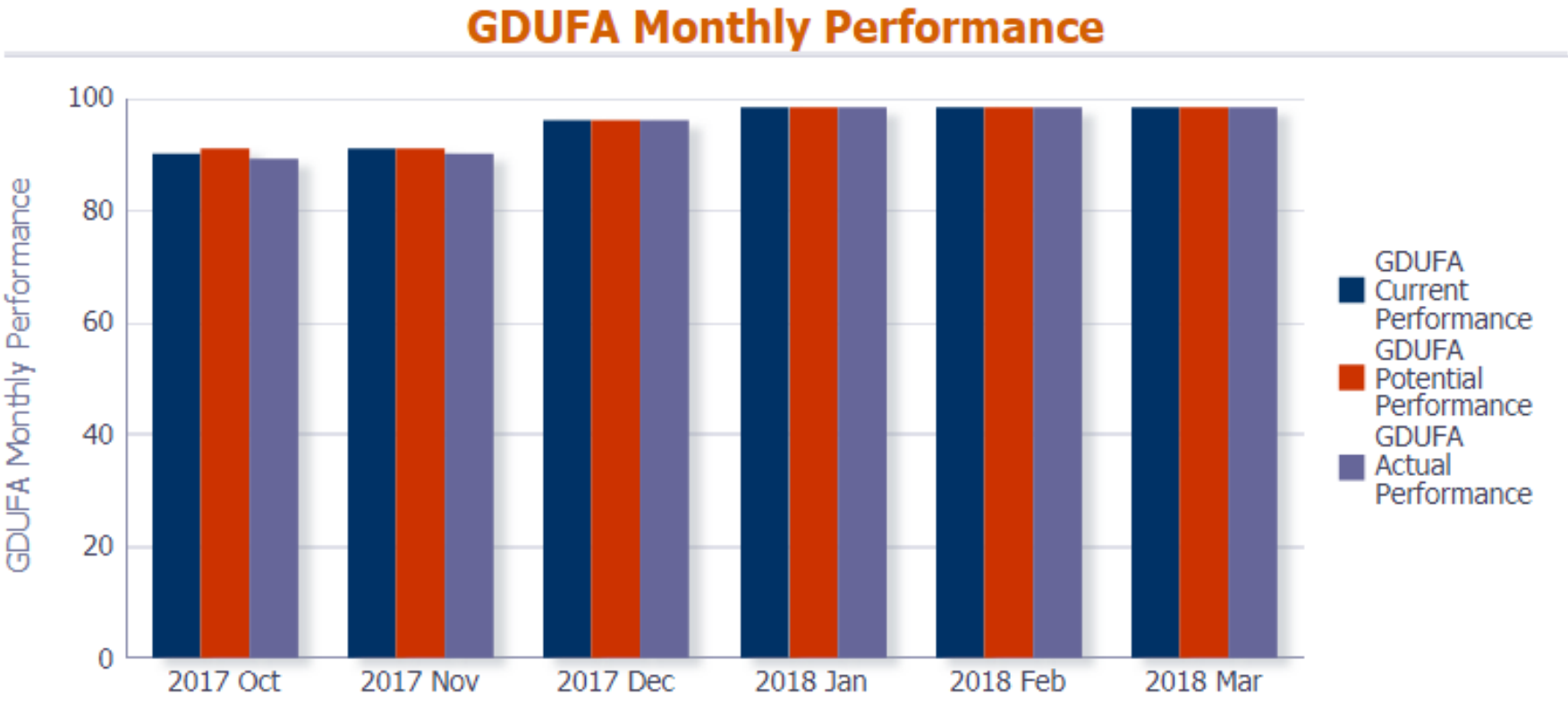
GDUFA II Metrics Scope

- Product Development & Pre-submission Meetings
- Controlled Correspondence
- Drug Master Files

GDUFA II Metrics Scope (cont.)

- ANDA Review
  - Original and Prior Approval Supplement review times
  - Discipline Review Letters (DRLs)
  - Mid-Review-Cycle Meetings/t-cons (for ANDA utilizing the pre-ANDA program)
  - Post-Complete Response Letter t-cons
  - AP Times
  - 1st Cycle Approvals/Tentative Approvals

GDUFA Review Goals Tracking



GDUFA II Metrics Scope (cont.)

- Requests for Reconsideration & Formal Dispute Resolution Requests
- Review Classification Changes
- Inspections
- Many more

Metrics Posted

- Activities Report of the Generic Drugs Program (FY2018) Monthly Performance
  - Actions
    - Applications
    - Drug Master Files
  - Receipts
    - Controls
    - PFCs
    - Applications

Metrics Posted (cont.)

- The Generic Drug Review Dashboard
  - Original ANDA Workload Activity for Pre-GDUFA Year 3 Application Cohorts
  - Total Original ANDA Workload Activity for All Unapproved Applications
  - Actions on Originals
  - Actions on Prior Approval Supplements

Metrics Posted (cont.)

- GDUFA Performance Reports
  - Comprehensive report posted yearly
  - GDUFA I Performance Reports archived

Concluding Remarks

- The ANDA program is in great shape!
  - Approval times are dropping
  - Time with FDA is dropping
  - Communications from FDA are increasing
  - Record Approvals/Tentative Approvals at the end of GDUFA I & beginning of GDUFA II
  - Exceeding GDUFA II goals
- It is a good time to submit an ANDA!

Thank you!