ANDA Program Statistics

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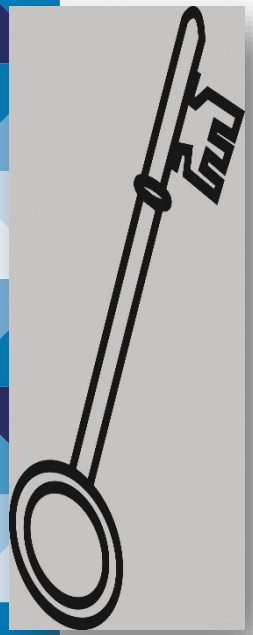
April 10, 2024

Learning Objectives

- Describe sources of ANDA Program statistics
- Provide insight on key statistics
- Show how to check goal date performance
- Share increasing interest in supplements

The Key to Access (Get it?)



- Objective
- Resources
- GDUFA III
- Best Practices
- Other Considerations

Statistical Resources

- Generic Drugs Program Monthly and Quarterly Activities Report
- Generic Drugs Program 2023 Fiscal Year Web Posting
- GDUFA Performance Report

Statistical Resources (cont.)

- Competitive Generic Therapy Approvals
- FDA-TRACK: Center for Drug Evaluation and Research - Pre-Approval Safety Review - Generics Dashboard

Fiscal Year (FY) Reporting

- Most metrics by Fiscal Year Oct.1–Sept.30
  - User Fee programs (including GDUFA)
  - Use reports to address official requests
    - Federal budget process
    - Congressional reporting

Generic Drugs Program Monthly and Quarterly Activities Report

- Actions by month
- Submissions by month
  - Originals
  - Supplements
- Approval times by quarter

Approval Time

APPROVAL TIMES BY QUARTER ^	Q1 (Oct - Dec 2022)	Q2 (Jan- Mar 2023)	Q3 (Apr - Jun 2023)	Q4 (Jul - Sept 2023)
Quarterly Mean Approval Times	28.82	38.11	35.09	34.65
Quarterly Median Approval Times	20.60	23.45	23.10	20.96
Quarterly Mean Tentative Approval Times	25.32	39.88	30.09	41.16
Quarterly Median Tentative Approval Times	20.31	36.76	25.36	24.74

Approval Time Calculation

- Time from Acknowledged/filed ANDA to Approval (AP) or Tentative approval (TA)
  - Excludes RTR (Refuse to Receive)
  - *Includes* industry response time
    - IRs (Information Requests)/DRLs (Discipline Review Letters)
    - CRLs (Complete Response Letters)

Approval Time Diagram

AP Time Calculation (cont.)

- Can there be subsequent AP or TA actions?

  Yes!

  -TA to AP conversions

  -TA to subsequent TA for changes

  -New strength AP

Mean and Median Approval Time Differences

- Quarter-to-Quarter variability expected
  - FDA assessment time
  - Cycles to AP/TA
  - Industry response time
  - Approval clusters

Mean and Median Approval Time Differences

- Mean (average) and Median (middle number) variability expected

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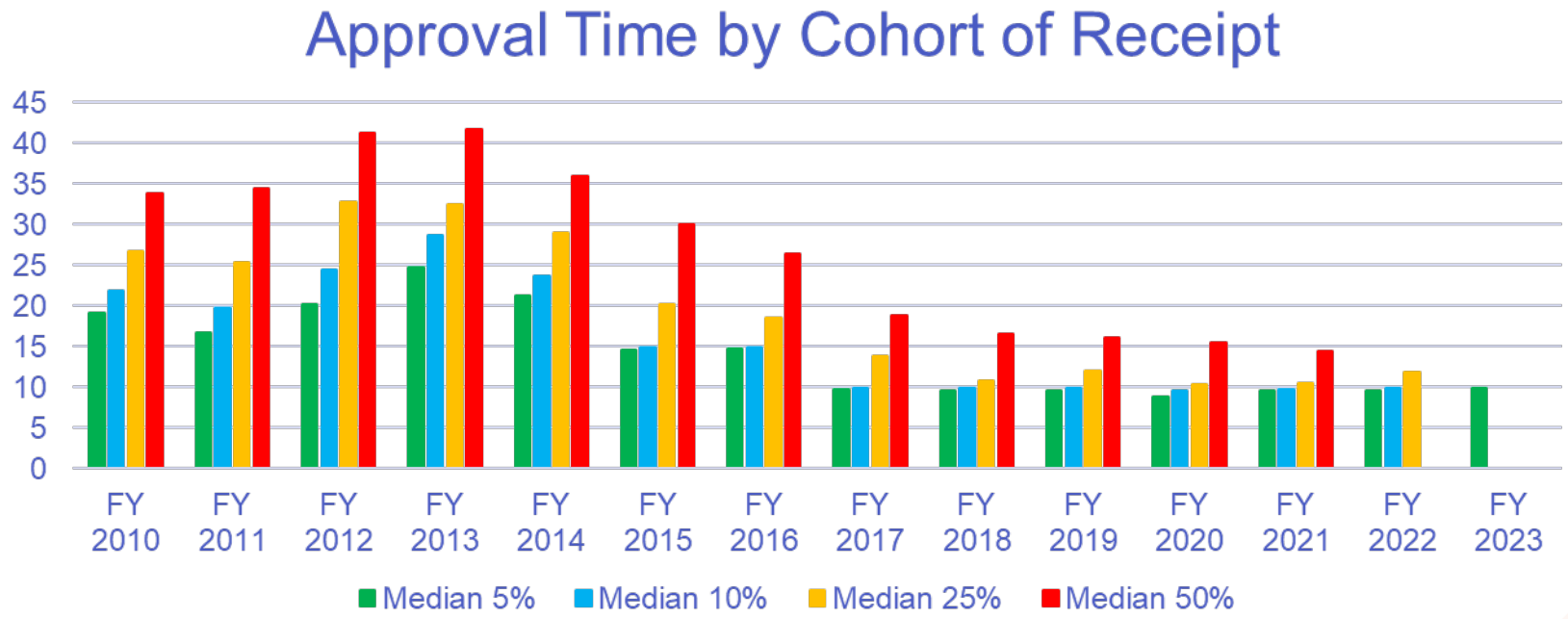
Quarterly Median Approval Times	20.60	23.45	23.10	20.96

- Mean time = old ANDAs trickling to AP
- Median time = new ANDAs flowing to AP

Approval Times



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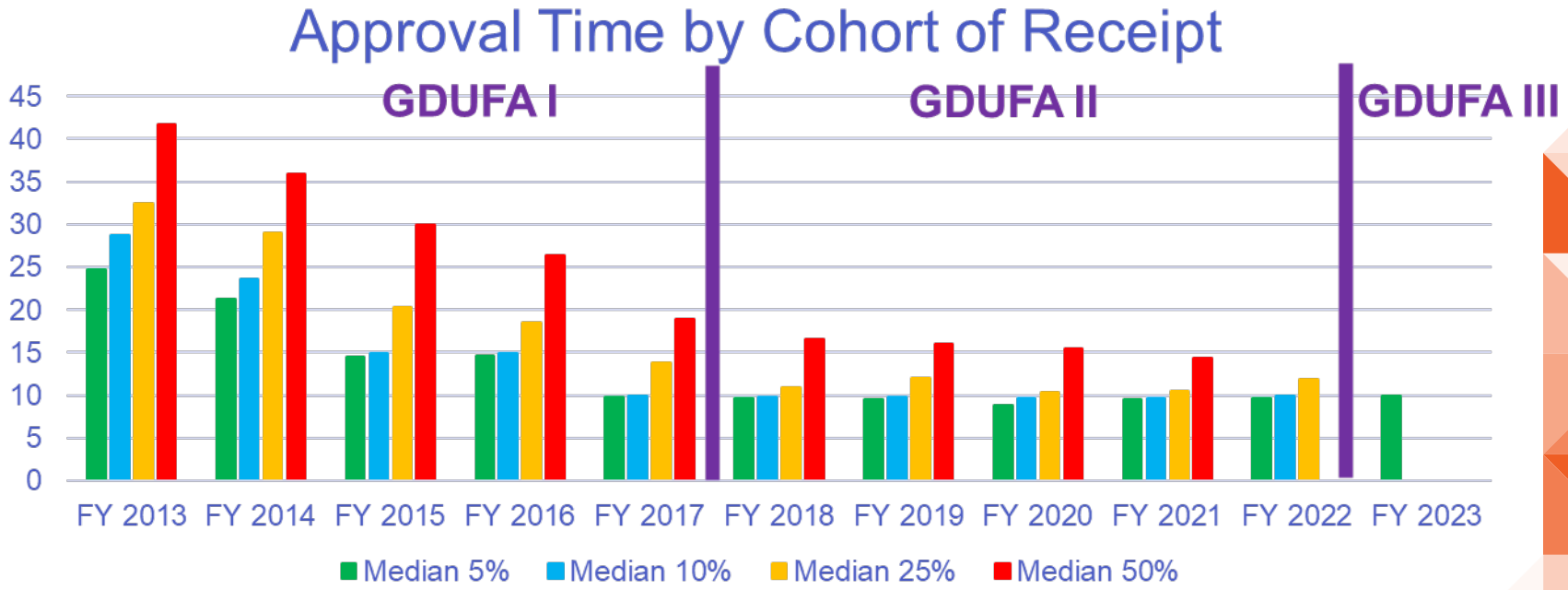
Approval Times (cont.)



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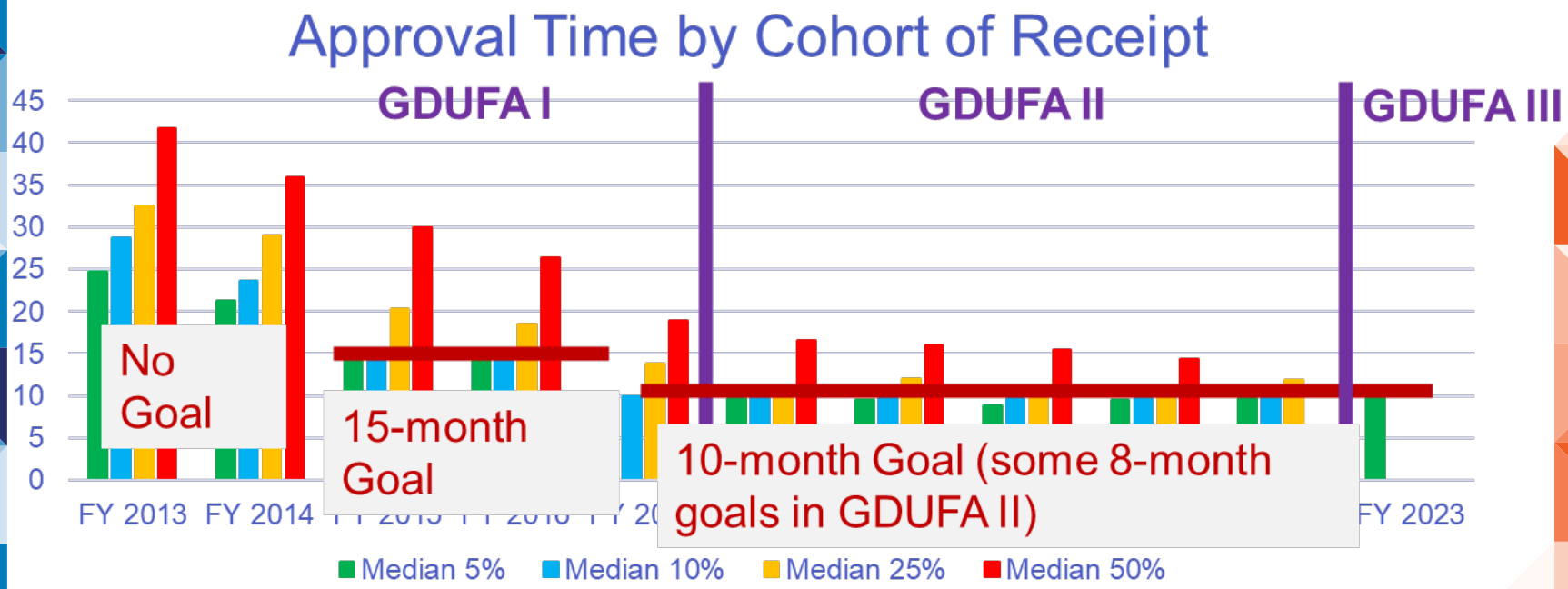

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Challenge Question #1

New application approval times are likely to be?

A. Longer than prior years

B. The same as prior years

C. Faster than prior years

Imminent Action (IA)

(formerly Imminent Approval)

1. Skipping a Tentative Approval (TA) by the goal date to facilitate final Approval (AP) within 60 days after the goal date
2. AP or TA an ANDA submitted by a first applicant by the 30-month forfeiture date

Imminent Action (cont.)

3. Bring ANDA with small issues to AP or TA

Best Practices:

- Respond to Information Requests on time
- Provide a thorough response
- Contact Regulatory Project Manager for ANDA status

3 Imminent Action (cont.)

- Harm to FDA: reduces TA counts
- Help to FDA:
  - **Mission is drugs available to patients**
  - **Imminent Action counts toward meeting goal date and 90% performance metric** (GDUFA III fix)

Imminent Action (cont.)

- Help to Industry:
  - Facilitates earliest market entry
  - Increases chance of approval on earliest lawful approval date (ELAD)
  - Takes worry out of submission timing

Imminent Action (cont.)

- Submission timing examples:
  - Weekend goal date but no ELAD = FDA issue AP prior business day (or sooner, if ready)

    Goal date Sat. 6 = FDA issue AP Fri. 5 (*or sooner*)

Imminent Action (cont.)

- ELAD on weekend = FDA must AP next business day

  ELAD date Sat. 6 = FDA issue AP Mon. 8

Imminent Action (cont.)

- Goal date just before an ELAD = FDA use Imminent Action (IA) to reach AP on ELAD (or next business day)

  Goal date Fri. 5, but ELAD Sat. 6 = FDA IA to AP Mon. 8th (rather than FDA issue TA on Fri. 5th delaying AP for weeks)

Imminent Action (cont.)

- Help to Patients:
  - **Facilitates *earliest* access to generics!**

Imminent Action (cont.)

ACTIONS BY MONTH	Oct-23
Approvals	57
First-Time Generics	4
First-Cycle Approvals	10
Imminent Actions	6

- Imminent Actions are a subset of the monthly approvals – 6 of the 57 APs
- Also applies to Tentative Approvals

Generic Drugs Program 2023 Fiscal Year Web Posting

- Original ANDA Review
- Amendment Review
- PAS Review
- PAS Amendment Review

Generic Drugs Program 2023 Fiscal Year Web Posting *(cont.)*

- GDUFA Meeting Commitments
- DMF Review
- Imminent Actions

How to Read the Report

	Review Time Goal	Actions Completed	Percent Completed on Time	Potential Range	On-Time Imminent Action +	Imminent Action Potential Range ++
Original ANDA Review						
Standard Original ANDA Submissions	10 months	76 of 511	93%	15% to 99%	100%	15% to 100%

- Based on data available at reporting date
- Modeled after GDUFA Performance Reports *to honor the Commitment Letter*

Performance Report vs Web

Table V. GDUFA FY 2022 Preliminary Review Goals

GDUFA FY 2022 Preliminary Review Goals by Submission Type	Review Time Goal	Actions Complete*	Percent on Time	Potential Range‡	On Time Imminent Approval	Imminent Approval Potential Range
Original ANDA Review						
Standard Original ANDA Submissions	10 months	89 of 553	99%	16% to 100%	100%	16% to 100%
Priority Original ANDA Submissions (if applicant meets requirements of a PFC)	8 months	18 of 43	100%	42% to 100%	100%	42% to 100%
Priority Original ANDA Submissions (if applicant does not meet requirements of a PFC)	10 months	29 of 149	100%	19% to 100%	100%	19% to 100%
Amendment Review						

Generic Drugs Program 2023 Fiscal Year Web Posting

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As outlined in the GDUFA III Commitment Letter, these GDUFA III performance metrics must be reported each fiscal year.

Original and PAS Review

	Review Time Goal	Actions Completed	Percent Completed on Time	Potential Range	On-Time Imminent Action +	Imminent Action Potential Range ++
Original ANDA Review						
Standard Original ANDA Submissions	10 months	76 of 511	93%	15% to 99%	100%	15% to 100%
Priority Original ANDA Submissions (if applicant meets requirements of a PFC)	8 months	8 of 24	78%	29% to 92%	100%	33% to 100%

What is different?

Some data moved from Performance Report to Web Posting – that's it

fda.gov/cdersbia

Why Move the Data

- Faster posting
- Responsibly focuses oversight on key metrics in GDUFA Performance Report

How to Read the Report (cont.)

- Potential Range – worst (miss all the remaining goal dates) and best (meet all the remaining goal dates) case scenarios

3 How to Read the Report (cont.)

- Imminent Action counts as **meeting goal!**
  - Commitment Letter II.B.3.b. If an ANDA is approved or tentatively approved within 60 days after the goal date, the **goal date will be considered to have been met.**

How to Read the Report (cont.)

	Review Time Goal	Actions Completed	Percent Completed on Time	Potential Range	On-Time Imminent Action +	Imminent Action Potential Range ++
Amendment Review						
Standard Major ANDA Amendments (if PAI is not required)	8 months	227 of 720	92%	31% to 99%	97%	31% to 99%
Standard Major ANDA Amendments (if PAI is required)	10 months	10 of 46	50%	13% to 86%	90%	20% to 98%

What is FDA measured on?

On-Time Imminent Action = 90%

(versus TA or *CRL* by goal date)

Challenge Question #2

Imminent Actions are reported as?

A. A subset of monthly AP and TA totals

B. Additive to monthly AP and TA totals

C. Future AP and TA actions

Challenge Question #3

Imminent Actions count as meeting the goal if?

A. ANDA AP or TA in subsequent cycle

B. ANDA AP or TA prior to goal date

C. ANDA AP or TA within 60 days of goal date

D. ANDA AP or TA 61 days after goal date

GDUFA Performance Report

- Workload
- Review Goals
- ANDA Review Program Enhancement Goals
- Pre-ANDA Program Goals

GDUFA Perform. Report (cont.)

- Drug Safety and Inspections Performance
- Performance Reporting
- Other information

Competitive Generic Therapy Approvals

- Approved ANDAs for drug products that received a Competitive Generic Therapy (CGT) designation
- Date of First Commercial Marketing of CGT with Exclusivity
- 260+ and going strong

FDA-TRACK: Center for Drug Evaluation and Research - Pre-Approval Safety Review - Generics Dashboard

- Cumulative Submissions
- Cumulative ANDA Approvals
- Cumulative ANDA CRs (Complete Response Letters)

FDA-TRACK: Center for Drug Evaluation and Research - Pre-Approval Safety Review - Generics Dashboard (cont.)

- Cumulative actions
- First Cycle Performance including with Imminent Action
- Cumulative Post CR Meetings and Letters

What to Watch

3 What to Watch (cont.)

- Fewer Complete Response Letters reported
  - ANDA program not healthy

    or

  - **Success of GDUFA III extensions**

3 What to Watch (cont.)

- Fewer solicited minor amendments received reported
  - ANDA program not healthy

    or

  - **Success of GDUFA III extensions**

What to Watch (cont.)

- Your ANDA Refuse to Receive rate is lower than average
  - **ANDA program is healthy** *and*
  - **Your ANDAs are healthy**
    - Using guidances and MAPPs
    - Using Pre-ANDA program communications

What to Watch (cont.)

- Your ANDAs experience fewer than average Complete Response Letters
  - **ANDA program is healthy** *and*
  - **Your ANDAs are healthy**
    - Clear and high quality
    - Good Drug Master File communications
    - Healthy facilities

What to Watch (cont.)

- Your ANDA is approved on ELAD
  - **ANDA program is healthy** *and*
  - **Your ANDA is healthy**
    - Fewer Complete Response Letters
    - Good Drug Master File communications
    - Healthy facilities

What to Watch (cont.)

- Your AP time lower than median
  - **ANDA program is healthy** *and*
  - **Your ANDA is healthy**
    - Fewer Complete Response Letters
    - Good Drug Master File communications
    - Healthy facilities

Increasing Interest in Supplements

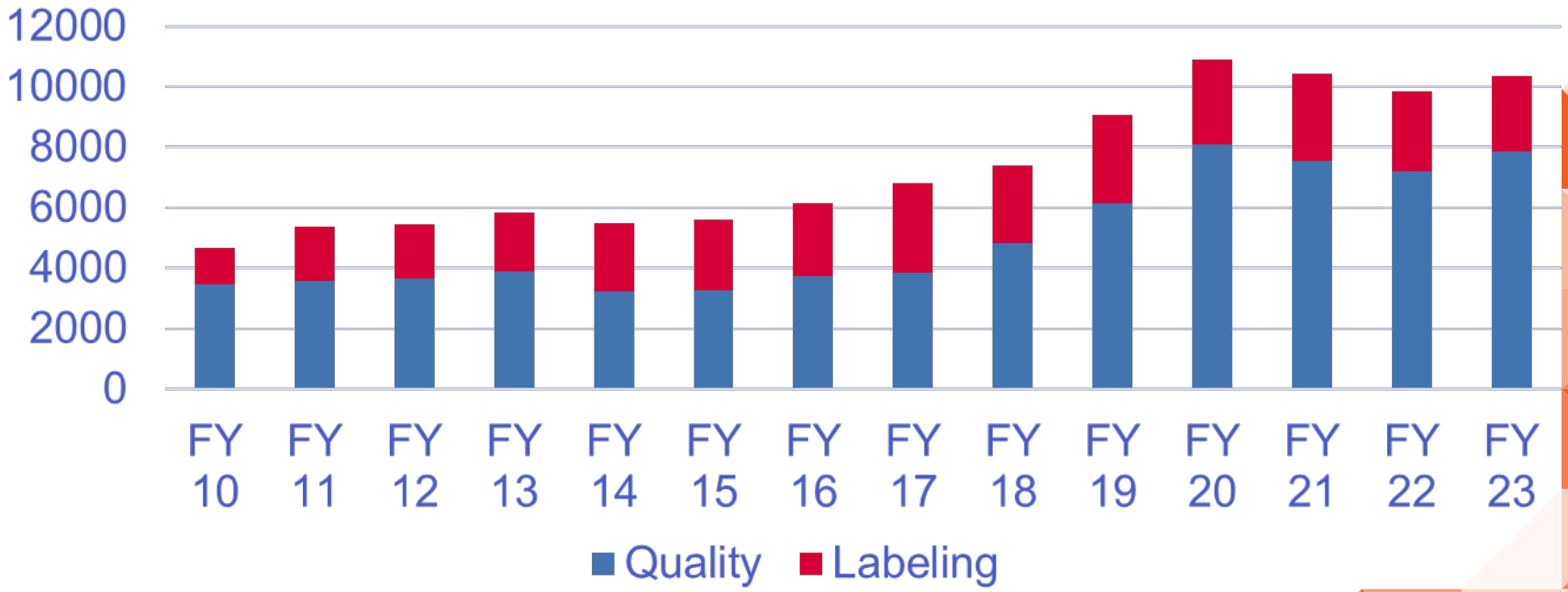
- More communications from industry
  - Type to submit
  - Status [including Changes Being Effected (CBEs)]
- >10,000 submitted in FY 23
  - 1,600 Prior Approval Supplements (PAS)

Increasing Interest in Supplements (cont.)

- Record year for approvals
- Approved more than received
- More interest and questions from Agency and higher

Quality and Labeling Supplements Received

(PAS and CBE)



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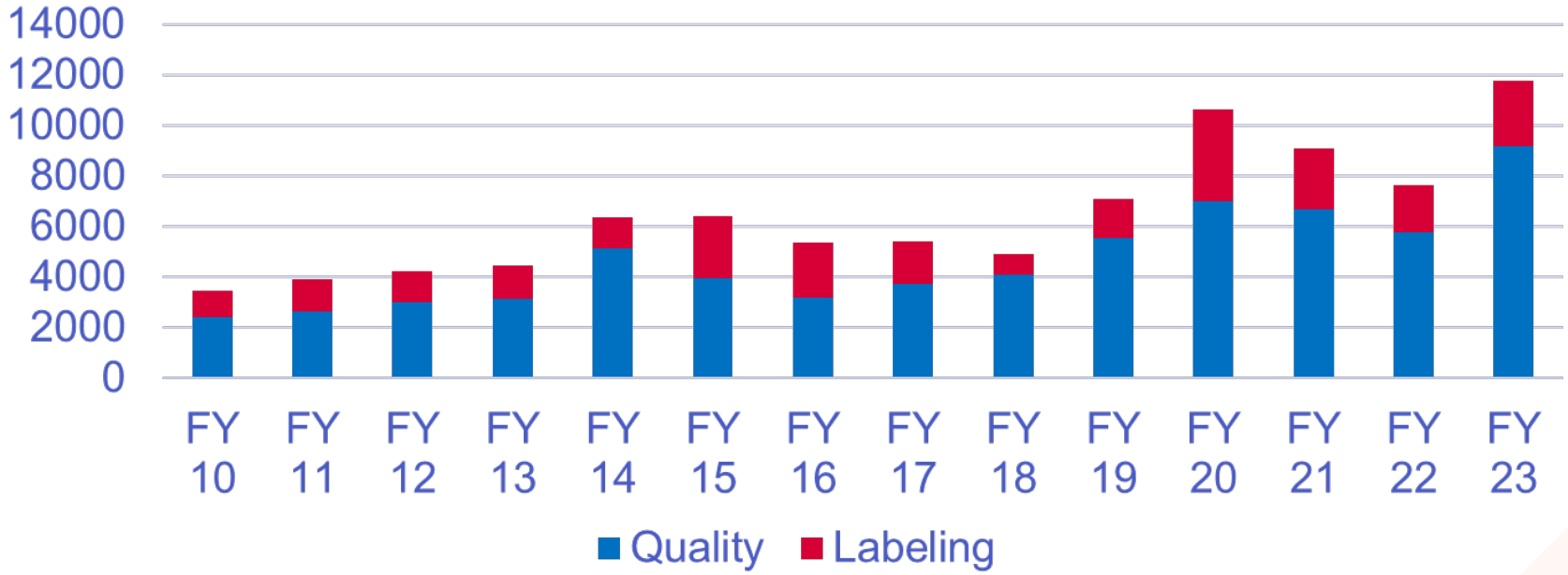
Quality and Labeling Supplements Approved

(PAS and CBE)



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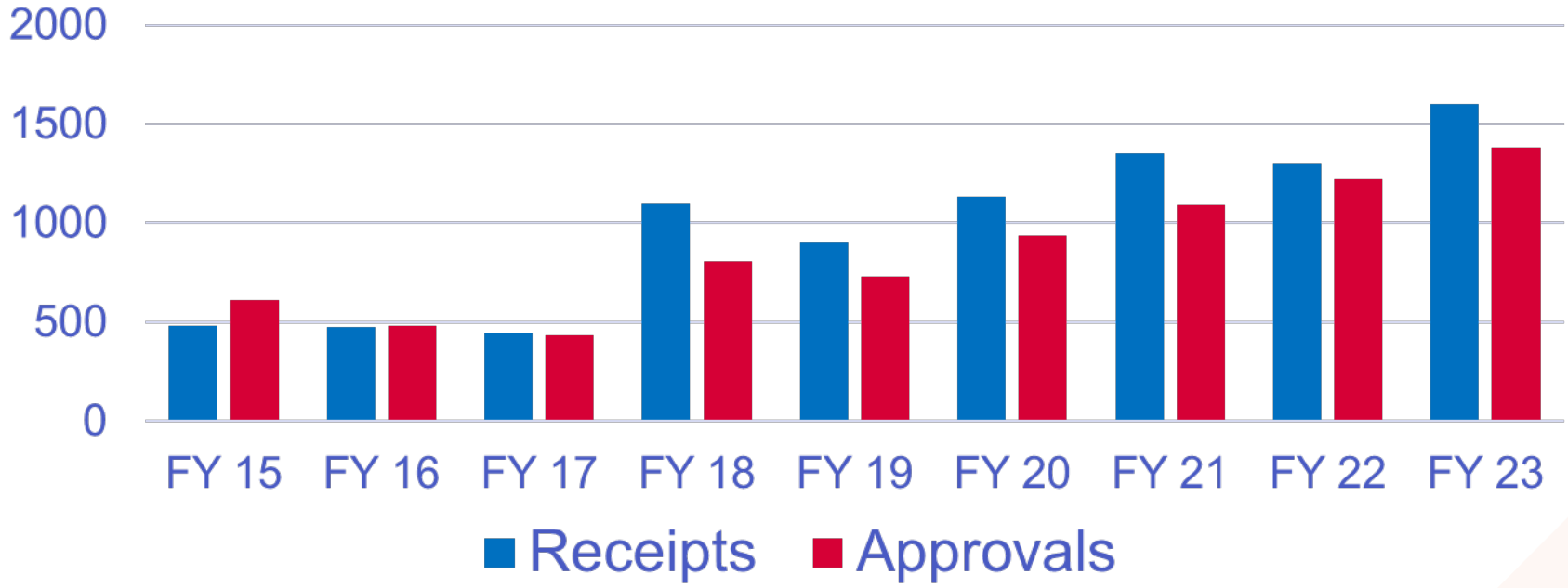
Prior Approval Supplements Receipts and Approvals



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Concluding Remarks

- Lots of data available
  - Success of GDUFA III
  - Health of ANDA program
  - Health of your program
- Good time to submit ANDAs!

Thank you!


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"When I reach for the medicine cabinet, I know I am safe, I am a patient, too!"
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