U.S. FOOD & DRUG ADMINISTRATION

GDUFA III Metrics

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Office of Generic Drugs
Center for Drug Evaluation and Research
April 12, 2023

Agenda

- GDUFA III Generic Drugs Monthly and Quarterly Activities Report
- Key Stats Explained
- Observations
- What to Watch

Learning Objectives

- Describe the layout of the new GDUFA III Generic Drugs Program Monthly and Quarterly Activities Report
- Recognize the salient metrics of the GDUFA III Program Monthly and Quarterly Activities Report

GDUFA III Generic Drugs Program Monthly and Quarterly Activities Report

Link: https://www.fda.gov/industry/generic-drug-user-fee-amendments/generic-drugs-program-monthly-and-quarterly-activities-report

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Generic Drugs Program Monthly and Quarterly Activities Report

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Generic Drug User Fee Amendments

- GDUFA III Reauthorization
- Pre ANDA Program
- ANDA Assessment Program
- Controlled Correspondence
- Drug Master File (DMF) Assessments
- Changes for Facilities
- User Fee Resource Management Program

With the start of GDUFA III in FY 2023, the Generic Drugs Program monthly and quarterly activities reports were combined into one report. Also, reported metrics have been updated to reflect reporting requirements outlined in the GDUFA III Commitment Letter.

Content current as of: 01/11/2023

Regulated Product(s): Drugs

ACTIONS BY MONTH	Oct-22	Nov-22	Dec-22	Jan-23	Feb-23	Mar-23	Apr-23	May-23	Jun-23	Jul-23	Aug-23	Sep-23	FY-2023
Approvals	58	60											118
First-Time Generics	1	3											4
First-Cycle Approvals	14	13											27
Imminent Actions	7	10											17
Tentative Approvals	13	13											26
First-Cycle Tentative Approvals	0	2											2
Imminent Actions	1	3											4
Complete Responses	148	120											268
Original ANDA Refuse to Receive	1	2											3
Standard	1	2											3
Priority	0	0											0

GDUFA III Generic Drugs Program Monthly and Quarterly Activities Report

- Activities Vs. Performance
- Updated Layout
- No More Preliminary Metrics Posting
- Updated Monthly
- Reporting More Data Earlier
- Exceeding GDUFA III Commitment Letter Requirements

- Merged Quarterly Reporting into One Monthly and Quarterly ***Activities*** Report
- Reporting more data earlier
- Exceeding GDUFA III Commitment Letter Requirements

GDUFA III Generic Drugs Program Monthly and Quarterly Activities Report

Monthly Actions

ACTIONS BY MONTH	Oct-22	Nov-22	Dec-22	Jan-23	Feb-23	Mar-23	Apr-23	May-23	Jun-23	Jul-23	Aug-23	Sep-23	FY-2023
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Complete Responses	146	122											268
Original ANDA Refuse to Receive	1	2											3
Standard	1	2											3
Priority	0	0											0
Original Acknowledgements	26	97											123
Withdrawals	3	9											12
Approved ANDA	0	0											0
Unapproved ANDA	3	9											12
PAS Approvals	117	96											213
PAS Refuse to Receives	0	0											0
PAS Withdrawals	5	7											12
Information Requests	297	324											621
Originals	178	209											387
Supplements	119	115											234
Discipline Review Letters	224	201											425
DMF Completeness Assessment	45	14											59
Reclassification of a Facility-Based Major CRL Granted	0	0											0
Reclassification of a Facility-Based Major CRL Denied	0	1											1
Pending ANDAs Awaiting FDA Action +	1504	1435											–
ANDAs Awaiting Applicant Action ++	2177	2144											–
Tentative Approvals +++	465	470											–
Complete Responses ++++	1708	1674											–

Monthly Submissions

SUBMISSIONS BY MONTH	Oct-22	Nov-22	Dec-22	Jan-23	Feb-23	Mar-23	Apr-23	May-23	Jun-23	Jul-23	Aug-23	Sep-23	FY-2023
ANDAs *	34	76											110
Complex Products	6	8											14
Amendments	187	247											434
Major	77	97											174
Minor	55	65											120
Unsolicited	55	85											140
Requests for Reclassification of a Facility-Based Major CRL Amendment	13	8											21
Pre-Submission Facility Correspondence	7	4											11
Supplements	693	727											1420
CBE	584	574											1158
PAS **	109	152											262
DMF Payments	14	22											36
Controlled Correspondence ***	267	303											570
Level 1	235	280											515
Level 2	32	23											55
Controlled Correspondence Requests for Clarification	2	2											4
Product Development Meetings	8	4											12
Pre-Submission Meetings	0	3											3
PSG Teleconferences	0	0											0
Pre-Submission PSG Meetings	0	0											0
Post-Submission PSG Meetings	0	0											0
Mid Cycle Review Meetings	0	0											0
Enhanced Mid Cycle Review Meetings	0	0											0
Post-CRL Clarification-Only Teleconferences	7	5											12
Post-CRL Scientific Meetings	3	0											3

Quarterly Approval Times

APPROVAL TIMES BY QUARTER ^	Q1 (Oct - Dec 2022)	Q2 (Jan- Mar 2023)	Q3 (Apr - Jun 2023)	Q4 (Jul - Sept 2023)
Quarterly Mean Approval Times				
Quarterly Median Approval Times				
Quarterly Mean Tentative Approval Times				
Quarterly Median Tentative Approval Times				

Notes and Abbreviations

NOTE: Numbers reflect current data at the time of posting and may change based on refreshed counts in our tracking systems, including application status updates. These numbers are not intended for Congressional reporting purposes. Indented metrics are included in the count of the non-indented metric above it.

Abbreviations:
ANDA = Abbreviated New Drug Application
PAS = Prior Approval Supplements
DMF = Drug Master File
CRL = Complete Response Letter
CBE = Changes Being Effected
PSG = Product-Specific Guidances

+ = Pending ANDAs Awaiting FDA Action are applications currently being reviewed by FDA. Many of these applications have been reviewed and found "not approvable" in a previous cycle and have been resubmitted by the applicant for another cycle of review and assessment. These metrics are calculated at the end of the month or just thereafter.

++ = ANDAs Awaiting Applicant Action represent a snapshot in time for the status of distinct original ANDAs. These metrics are calculated at the end of the month or just thereafter.

+++ = ANDAs Awaiting Applicant TA are applications that have a status of 'TA' or Tentative Approval. If a generic drug product is ready for approval but cannot be approved due to a patent or exclusivity related to the reference listed drug product, FDA issues a tentative approval letter to the applicant, and the tentative approval letter details the basis for the tentative approval. A tentative approval does not allow the applicant to market the generic drug product in the United States. The Federal Food, Drug, and Cosmetic Act (FD&C Act) delays final approval of the generic drug product until all patent or exclusivity issues have been resolved or, in some cases, until a 30-month stay associated with patent litigation has expired.

++++ = Applications Awaiting Applicant Action are applications that have a status of 'CR' or Complete Response. These applications have been reviewed by FDA and the data submitted are inadequate to support approval.

* = Original Receipts are reported as raw receipts (versus filed receipts).
** = PAS Supplements do not include REMS PAS supplements.
*** = Controls count only those requests deemed appropriate for a control.

^ = Mean/ Median AP/TA calculated as the difference between the first full approval (AP) date or the first Tentative Approval (TA) date and the date the original application was accepted for filing divided by the average number of days per month (30.4375). The unit for each of these metrics is months.

GDUFA III Generic Drugs Program Monthly and Quarterly Activities Report

Monthly Actions

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Imminent Actions	1	3
Complete Responses	148	120

- Approvals, Tentative Approvals, and Complete Reponses are now listed first (these were the old preliminary metrics)
- Imminent Actions for Approvals and Tentative Approvals (***This is an annual requirement that we're posting monthly)***

Pending ANDAs Awaiting FDA Action +	1584	1615
ANDAs Awaiting Applicant Action ++	2177	2144
Tentative Approvals +++	469	470
Complete Responses ++++	1708	1674

- ANDAs awaiting FDA and Applicant actions are now listed monthly (***This is a quarterly requirement that we're posting monthly)***

GDUFA III Generic Drugs Program Monthly and Quarterly Activities Report

Monthly Submissions

SUBMISSIONS BY MONTH	Oct-22	Nov-22	Dec-22	Jan-23	Feb-23	Mar-23	Apr-23	May-23	Jun-23	Jul-23	Aug-23	Sep-23	FY-2023
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Post-CRL Scientific Meetings	3	0											3

ANDAs *	34	76
Complex Products	6	8

- Complex Products (***This is a quarterly requirement that we're posting monthly***)

Product Development Meetings	8	4
Pre-Submission Meetings	0	3
PSG Teleconferences	0	0
Pre-Submission PSG Meetings	0	0
Post-Submission PSG Meetings	0	0
Mid Cycle Review Meetings	0	0
Enhanced Mid Cycle Review Meetings	0	0
Post-CRL Clarification-Only Teleconferences	7	5
Post-CRL Scientific Meetings	3	0

- Meetings / Teleconferences (***This is an annual requirement that we're posting monthly***)

Challenge Question #1

In the New Generic Drugs Program Monthly and Quarterly Activities Report, Approvals are listed:

A. First

B. Third

C. Last

D. None of the above

Key Stats Explained

Fiscal Year Reporting

- Majority of metrics by Fiscal Year (FY) Oct. 1 – Sept. 30
  - Alignment with Federal budget and prep process
  - Congressional reporting
  - Generic Drug User Fee Amendments Commitment Letter
- Use Monthly and Quarterly Activities Reports to address official stats requests
- Exceptions include OGD Annual Report (Calendar Year)

Tentative Approvals

- Definition: “If a generic drug product is ready for approval but cannot be approved due to a patent or exclusivity related to the reference listed drug product, FDA issues a tentative approval letter to the applicant…”
- What is counted: Tentative Approval (TA) letters issued

Tentative Approvals (cont.)

- Can one ANDA received multiple TAs?
  - Yes
- When are subsequent TAs issued?
  - Post-TA amendment submitted with new FDA decision of TA
- What types of information are submitted?
  - Small updates to “Major” changes

Tentative Approvals (cont.)

- Why are subsequent TAs counted?
  - Easier to count letters issued
  - Amendment triggering GDUFA goal date submitted
  - FDA resources expended and accounting requirements
  - FDA approval level endorsement required
  - FDA action in advance of full approval (AP) conversion request
  - Facilitates AP on earliest lawful approval date (ELAD)
  - Patient protection: President's Emergency Plan for AIDS Relief

Imminent Action

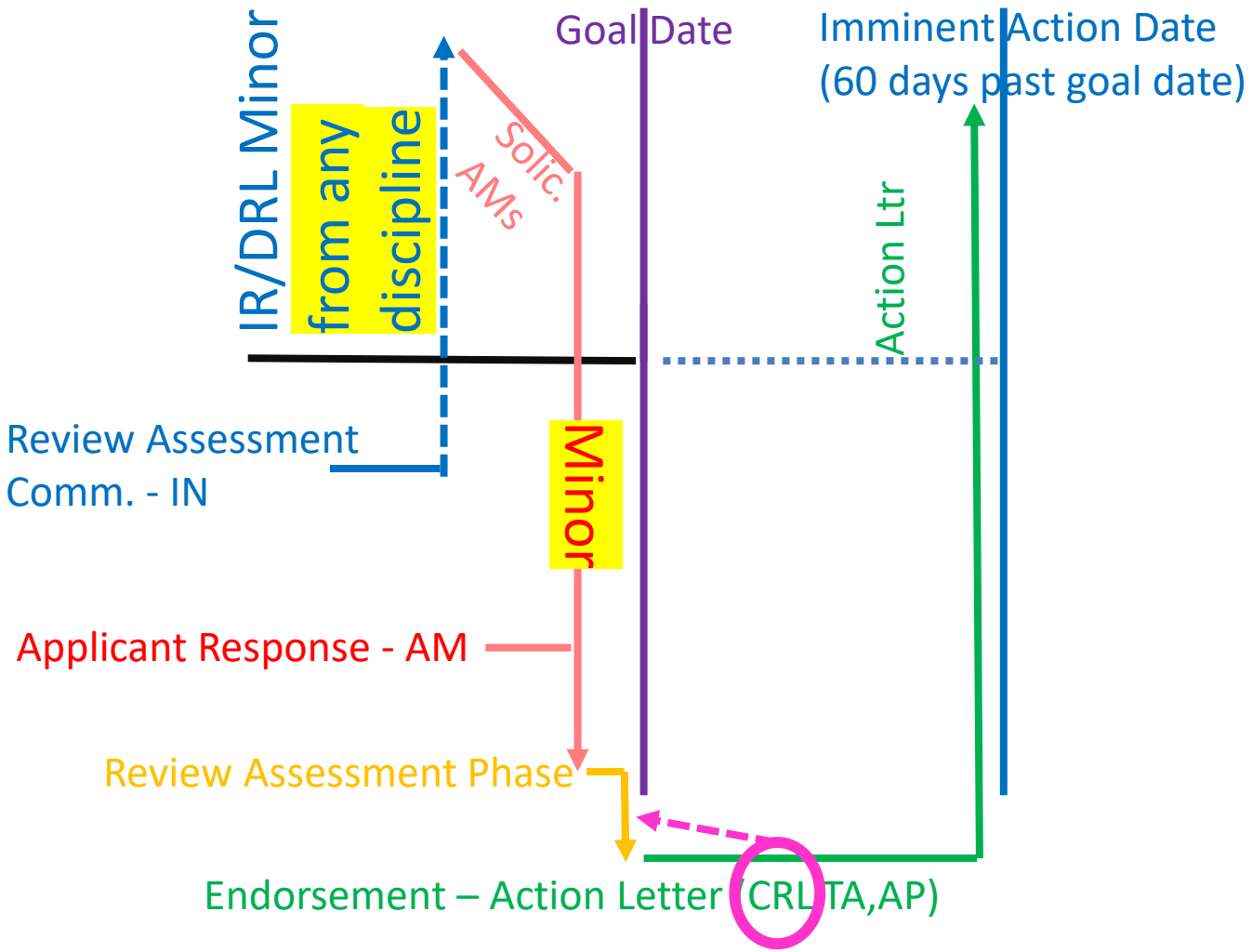
(formerly Imminent Approval)

1. Skipping a Tentative Approval (TA) by the goal date to facilitate full 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 an ANDA with one or more small issues to AP or TA



Tips:

1. Respond on time
2. Thorough response
3. Alert discipline PM of issues w/ IR/DRL response
4. Contact RPM for ANDA status questions

ACK = Acknowledgement Letter
AD = (Discipline) Adequate
IN = (Discipline) Inadequate
AM = Amendment

Imminent Action (cont.)

- Harm to FDA
  - Reduces FDA TA counts
- Help to FDA
  - Reduces number of endorsement packages
- Help to Industry
  - Increases chance of AP and on ELAD
  - Facilitates earliest market entry
- Help to Patients
  - Facilitates patient access to cost high quality generics!

Approval Time Calculation

- Definition
  - Mean: average (months to action)
  - Median: middle number (of months to action)
- How calculated?
  - Time to first AP or TA action
- Are there subsequent AP or TA actions?
  - Yes, increasing TA to AP, subsequent TAs, split AP and TA

Mean and Median Approval Time Differences

- Quarter-to-Quarter variability expected
  - FDA assessment time
  - Cycles to AP/TA
  - Industry response time
  - ELAD clusters
- Slower mean - older ANDA APs raise average
- Faster median - newer ANDA AP time dropping (1st cycle AP/TAs)

Observations

Program Health

- Often hear receipts vs approvals
- Original ANDA view

ANDA receipts. vs. Refuse to Receive + Withdrawal UnAP + AP

857 vs. 49 + 121 + 722

857 in vs. 892 out

(Monthly and Quarterly Activities Report data used for all metrics)

- Program bigger than Originals (e.g., research, controls, post-AP)

Increasing Interest in Supplements

- More communications from industry related to supplements
  - Type to submit
  - Status (including CBEs)
- Nearly 10,000 submitted in FY 22
  - Nearly 1,300 PAS
- More questions from Agency and higher

Imminent Actions (IAs)

- Not just for FDA to meet a goal date
- Industry align goal dates with ELAD
  - Weekend goal date – FDA issue action prior business day

    Goal date is Sat. 6th, no ELAD – FDA issue AP Fri. 5th *or earlier*
  - ELAD on weekend – FDA only AP next business day

    ELAD date is Sat. 6th – FDA issue AP Mon. 8th
  - Goal date just before an ELAD – IA to reach AP on ELAD

    Goal date is Fri. 5th but ELAD Sat. 6th – FDA IA to AP Mon. 8th

What to Watch

What to Watch

- New GDUFA III Performance Report
- New GDUFA III Fiscal Year Web Posting
- Median TA/AP time drop = new ANDAs flowing
- Fewer Complete Response Letters reported
  - ANDA program not healthy

    or
  - **Success of GDUFA III extensions**

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 Regulatory Affairs Dept. is healthy**
    - Using guidances and MAPPs
    - Using Pre-ANDA program communications

What to Watch (cont.)

- Your ANDAs experience fewer than average missed goal dates
  - ANDA program is healthy

    and
  - **Your ANDAs are healthy**
    - Clear and high quality
    - Healthy facilities and Drug Master Files
    - Good communications with Drug Master Files

What to Watch (cont.)

- Your ANDA is approved on ELAD
  - ANDA program is healthy

    and
  - **Your ANDA is healthy**
    - Fewer Complete Response Letter majors and more extensions
    - Fewer cycles to approval – accuracy vs. rapid response time
    - Healthy facilities and Drug Master Files
    - Good communications with Drug Master Files

What to Watch (cont.)

- Your company's AP time lower than mean and median
  - ANDA program is healthy

    and
  - **Your ANDAs are healthy**
    - Fewer Complete Response Letter majors and more extensions
    - Fewer cycles to approval – accuracy vs. rapid response time
    - Healthy facilities and Drug Master Files
    - Good communications with Drug Master Files

What to Watch (cont.)

- Goal date is Fri. 5th, ELAD is Sat. 6th, no AP on Fri. 5th
  - ANDA program is healthy

    and
  - **Imminent Action for Mon. 8th**
    - Check with your Regulatory Project Manager
    - Check company champaign supply

Challenge Question #2

Imminent Actions count as meeting the goal if?

A. The ANDA is AP or TA in a subsequent cycle

B. The ANDA is AP or TA prior to the goal date

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

D. The ANDA is AP or TA 61 days after the goal date

Concluding Remarks

- Lots of data available
  - Assess success of GDUFA III (e.g., fewer minor amendments)
  - Assess health of program (e.g., meeting goals)
  - Assess health of your company (e.g., APs taking less time)
- ANDA Program is healthy

Thank you!

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