

ANDA Missed Goal Dates

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Learning Objectives



- Describe a missed goal date
- What happens with a miss
- Causes of missed goal dates
- Public information

Background



- FDA hears frustration with misses
- FDA apologizes for misses
- FDA does not like misses
- FDA never gives up on an ANDA

What is a Goal Date?



- **Completion** and **communication** date
 - All discipline assessments
 - All facility evaluations (includes inspections and equivalents)
 - Letter issued

Goal Dates Not Approval Dates

- Assessors & PMs want approvals
- Approvals often easier for assessors
- FDA wants high approval counts
- FDA desires approvals on the earliest lawful approval date (ELAD)
- FDA mandates appropriate approvals

What is a Goal Date Miss



- FDA did not complete and communicate by the **current** goal date
 - May include extensions (noted in Acknowledgement Letters)
 - May be the longer of two goal dates from Acknowledgement Letter

Acknowledgement Letter



“...the GDUFA goal date for review of this priority major amendment is **June 20, 2024**. If FDA determines that an inspection is required to validate the information contained in this priority major amendment and a Pre-Submission Facility Correspondence was not submitted or not accepted, the GDUFA goal date for review of this priority major amendment is **October 20, 2024**.”

Acknowledgement Letter (cont.)



“...the GDUFA goal date...is **June 20, 2024**. If FDA determines that an inspection is required...the GDUFA goal date for review of this priority major amendment is **October 20, 2024**.”

- Oct. 1 AP (with inspection/equivalent) is a **make!**
- Oct. 31 CRL is a **miss**
- Oct. 31 AP is a **make!** (Imminent Action)

Acknowledgement Letter (cont.)



“...the GDUFA goal date...is June 21, 2024. If FDA determines that an inspection is required...the GDUFA goal date for review of this priority major amendment is October 21, 2024.”

- Oct. 1 AP (with inspection/equivalent) is a **make!**
 - Inspection on Sept. 1 - **make!**
 - Inspection on May 1 - **make!**

What Happens with a Miss



- Internal alerts prior to goal date
 - Discipline Project Manager (PM) to Regulatory Project Manager (RPM)
 - Command Center
 - Letter Signers

What Happens with a Miss (cont.)

- Command Center
 - Managed by Office of Regulatory Operations
 - Discipline Project Manager ANDA reporting
 - Advanced warning of potential misses – some misses are prevented
 - Extra coordination of drug shortage and Public Health Emergency ANDAs

What Happens with a Miss (cont.)

- Command Center (cont.)
 - Evaluation of original ANDA receipts:
 - Potential filing delays
 - Priorities
 - Pre-Submission Facility Correspondence
 - Complex
 - Mid-cycle review meeting ANDAs
- Combination product

What Happens with a Miss (cont.)

- Command Center (cont.)
 - Evaluation of original ANDA receipts:
 - Potential filing delay examples:
 - Eligible for 505(j)
 - Formulation appropriate
 - User fee payment status

What Happens with a Miss (cont.)

- After goal date
 - Senior Command Center
 - OGD leadership notification
 - Misses
 - Misses at 60 days
 - “must have” applications

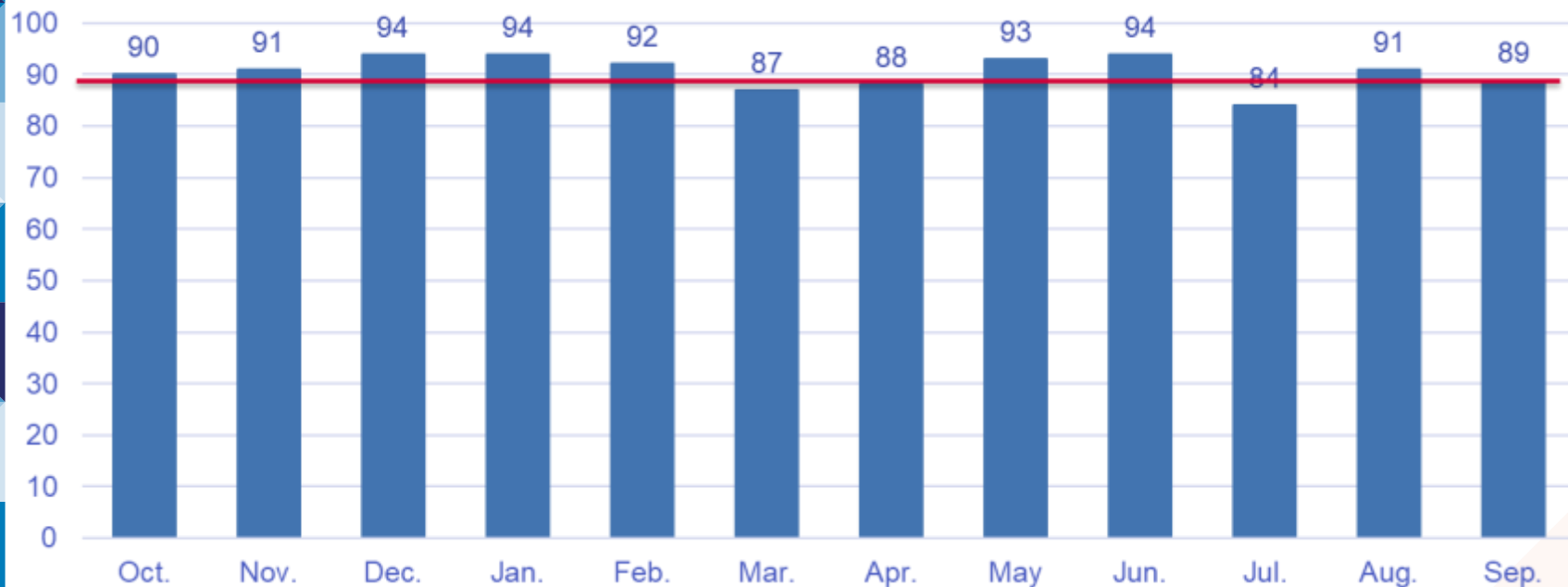
What Happens with a Miss (cont.)

- Senior Command Center
 - Managed by Office of Regulatory Operations
 - Review of prior month's misses
 - Program level stats
 - ANDA specific reasons
 - Controlled Correspondence data

Charts from Senior Command Center

GDUFA Goal % Achieved

Note: Excludes Imminent Action



Imminent Action

- 83 of 694 APs
- 36 of 162 TAs

TA = Tentative Approval

Generic Drugs Program Activities Report - FY 2024 Monthly Performance



ACTIONS BY MONTH	Oct-23	Nov-23	Dec-23	Jan-24	Feb-24	Mar-24	Apr-24	May-24	Jun-24	Jul-24	Aug-24	Sep-24	FY-2024
Approvals	57	51	53	56	52	48	65	71	50	63	65	63	694
First-Time Generics	4	4	4	6	7	2	10	12	4	6	8	3	70
First-Cycle Approvals	10	6	12	9	13	7	19	7	9	12	9	9	122
Imminent Actions	6	7	9	5	5	7	8	7	3	10	11	5	83
Tentative Approvals	16	17	11	17	11	13	12	13	15	12	14	11	162
First-Cycle Tentative Approvals	4	0	0	0	2	1	2	2	0	1	3	0	15
Imminent Actions	4	5	5	2	1	4	4	3	1	0	5	2	36

fd: A subset of monthly AP & TA totals.

ANDA Examination



Project/ Application Number	Submission Status	Submission Status Effective Date	Goal Date	Note	Established Name	Project Owner	Project Description
	Pending			pending			Imminent Action - Labeling Rescue - Late cycle Labeling DRL issued DATE
	Approved			missed			Imminent Action - ELAD DATE
	Approved			missed			Imminent Action - ELAD DATE
	Pending			pending			Missed goal date - XXXXX-hold. CR Major notification to applicant on XX/YY Changed Owner Due Date to WW/XX/ZZZZ per John Smith email.
	Approved			missed			Imminent Action- ELAD DATE
	Pending			pending			Missed goal date: Pending forfeiture analysis.
	Pending			pending			Missed Goal Date. Late consult (review of ZZZZ data)
	Approved			missed			Imminent Action - ELAD DATE
	Approved			missed			Missed goal date - EVENT occurred after the Goal Date
	Approved			missed			Imminent Action - ELAD DATE
	Approved			missed			Imminent Action. Skipping CR for an Approval
	Approved			missed			Imminent Action - ELAD DATE
	Pending			pending			Missed Goal date - due to pending DISCIPLINE review.DISCIPLINE propose applicant DATE will be CR.

Prior-Approval Supplements



GDUFA dates 10/1/23-9/30/24

PAS (Initial PAS submission)	# Due	# On Time	% On Time
Standard PAS with 10 month goal (inspection	64	62	97%
Standard PAS with 6 month goal (no	1569	1539	98%
Priority PAS with 10 month goal (inspection	9	9	100%
Priority PAS with 8 month goal (inspection needed and PFC	1	1	n/a
Priority PAS with 4 month goal (no	104	100	96%

Causes of Missed Goal Dates



- Thorny Regulatory Issues (e.g., policy issues, *exclusivity documentation*, data integrity)
- Facilities issues
- Inspection needed
- Lifecycle (e.g., brand safety and efficacy, labeling)
- Program error (e.g., missed triage, late consult)
 - Cover Letter Attachment helps

Cover Letter Attachment



Cover Letter Attachments for Controlled Correspondence and ANDA Submissions Guidance for Industry

Link: <https://www.fda.gov/media/154762/download>

Challenge Question #1



What happens with a missed goal date?

- A. FDA moves to the next ANDA
- B. FDA withdraws the ANDA
- C. FDA never gives up on an ANDA

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

Public Information



- GDUFA Performance Report
- Generic Drugs Program 202X Fiscal Year Web Posting
- FDA-TRACK: Center for Drug Evaluation and Research - Pre-Approval Safety Review - Generics Dashboard

GDUFA Performance Report



GDUFA II FY 2022 Updated Performance Goals by Submission Type	Review and Act on 90 % Within	Actions Complete*	Percent on Time	Potential Range†	On Time Imminent Action	Imminent Action Potential Range
Original ANDA Goals						
Standard Original ANDA Submissions	10 months	574 of 628	93%	87% to 93%	95%	89% to 96%
Priority Original ANDA Submissions (if applicant meets requirements of a PFC)	8 months	41 of 41	95%	95% to 95%	98%	98% to 98%

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

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.)



GDUFA II FY 2022 Updated Performance Goals by Submission Type	Review and Act on 90 % Within	Actions Complete*	Percent on <u>Time</u>	Potential Range [†]	On Time Imminent Action	Imminent Action Potential Range
Original ANDA Goals						
Standard Original ANDA Submissions	10 months	574 of 628	93%	87% to 93%	95%	89% to 96%
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What is FDA measured on?

On-Time Imminent Action = 90%
(versus TA or CRL by goal date)


Fiscal Year Web Posting



- Outgrowth of Performance Report
- Similar layout to Performance Report
 - Percent Completed on Time
 - On-Time Imminent Action



FDA-TRACK... Generics Dashboard

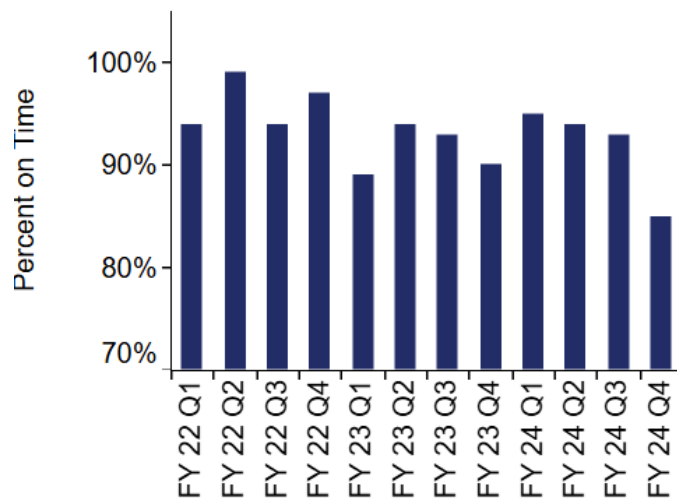
- Specific to First Cycle Performance
 - First Cycle Performance
 - First Cycle Performance Adjusted for Imminent or Tentative Approval
 - Based on goals dates (not the same metric as in the GDUFA Performance Report)
- 

FDA-TRACK... Generics Dashboard



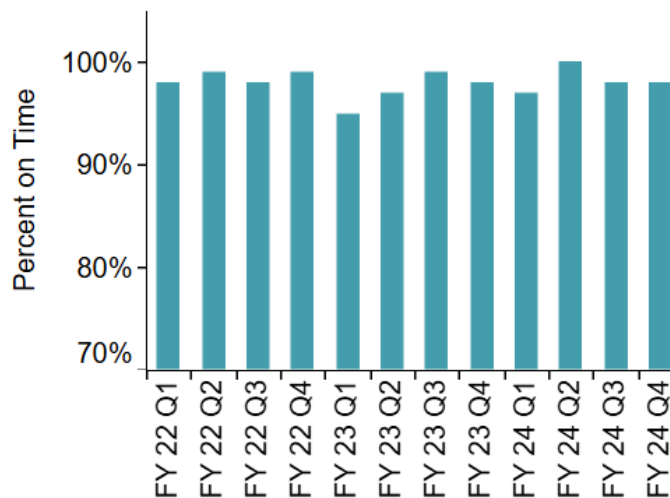
First Cycle Performance
as of FY24 Q4

85%



First Cycle Performance Adjusted
for Imminent or Tentative
Approval as of FY24 Q4

98%



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

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!



We Are OGD

Ask me why...

"We **monitor** the **safety** of **generic** drugs for as long as they are in the market."

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

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