Mid-Review Cycle Meetings

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Generic Drugs Forum 2021 – April 29, 2021

Learning Objectives

- Definition of Mid-Review Cycle Meeting (MRCM)
- Goals of MRCM
- MRCM Categories
- Meeting Agenda
- How MRCMs are Scheduled
- How MRCMs are Conducted
- Rescheduling or Canceling MRCMs
- Timeline (Process Overview)
- Tips for Applicants
- Fictional Cases

Mid-Review Cycle Meeting Defined

Mid-Review Cycle Meeting

A Mid-Review Cycle Meeting (MRCM) is a 30-minute telephone conference held at the mid-point of the first review cycle

Goals


convey, to applicants, key issues or concerns that were identified during the Abbreviated New Drug Application (ANDA) review
ask applicants clarifying questions about the submission
outline recommended next steps for applicants

MRCM Categories

Complex ANDAs

- As described in the Generic Drug User Fee Amendments (GDUFA) II Commitment Letter, FDA offers MRCMs to applicants who were granted pre-ANDA meetings (i.e., product development meetings and/or pre-submission meetings)

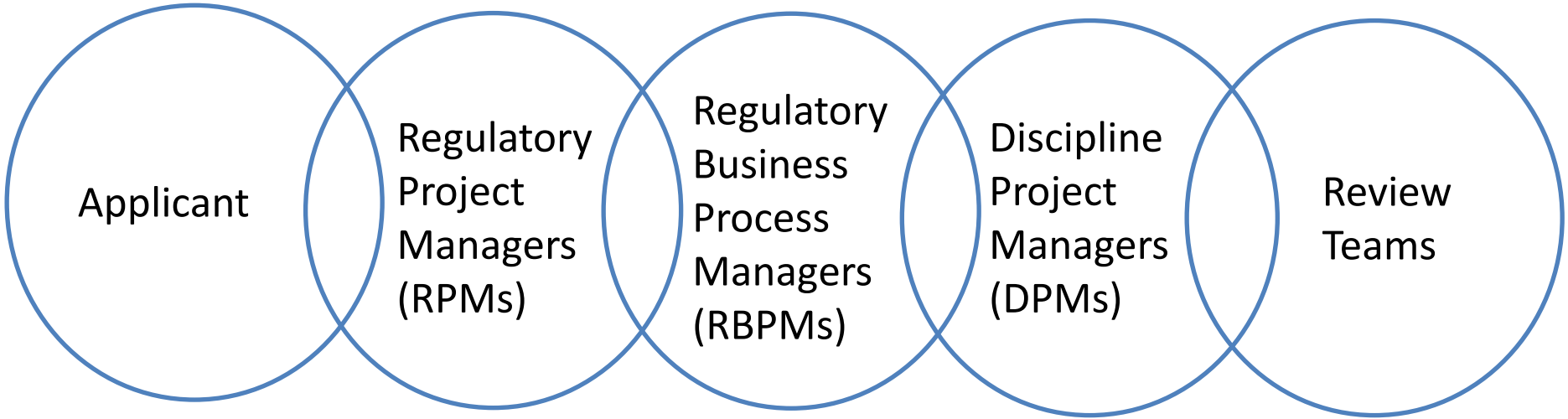
Competitive Generic Therapy ANDAs

- Per Competitive Generic Therapy (CGT) Guidance, FDA may offer an MRCM for CGT-designated ANDAs

Complex Product Examples

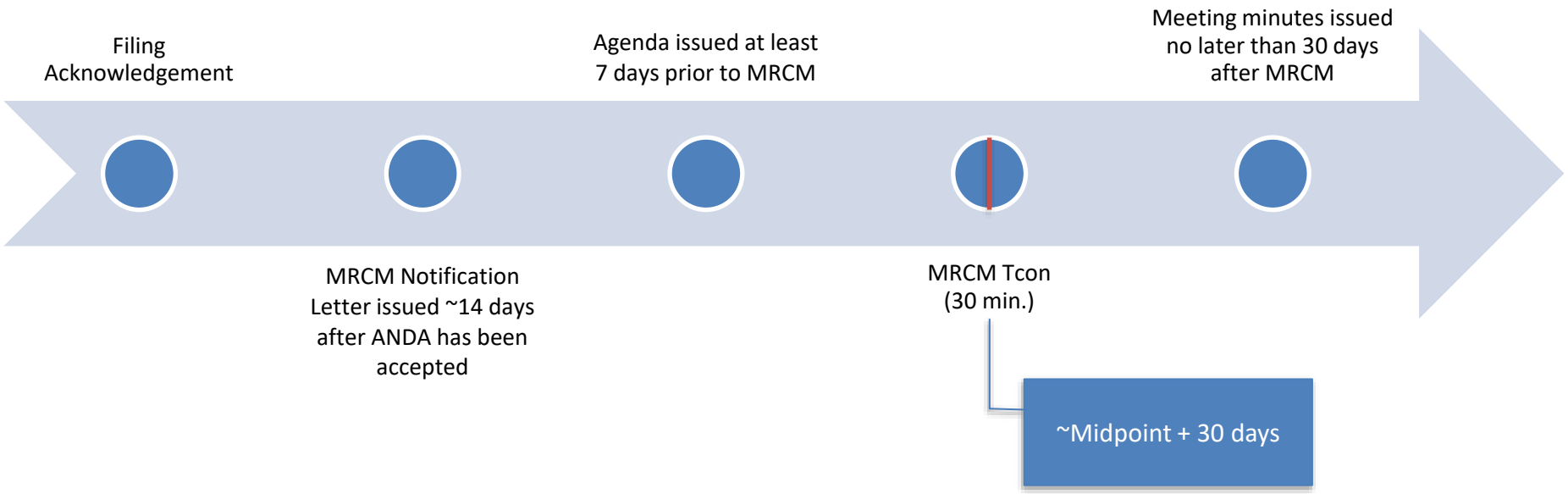
COMPLEX…	Example
Active ingredients	Peptides, complex mixtures, natural source products
Formulations	Liposomes, emulsions
Routes of Delivery	Locally acting drugs such as dermatological products and complex ophthalmological products
Dosage Forms	Transdermal systems, extended release injectables
Drug-Device Combinations	Auto-injectors, metered dose inhalers
Other products	Complexity or uncertainty concerning the approval pathway or possible alternative approach would benefit from early scientific engagement

MRCM Attendees



How MRCMs are Scheduled

MRCM Scheduling Timeline



Meeting Notification Letter

ANDA ######

MID-REVIEW-CYCLE MEETING NOTIFICATION

APPLICANT NAME
APPLICANT ADDRESS
Attention: CONTACT NAME
CONTACT TITLE

Dear Sir or Madam:

This is in reference to your abbreviated new drug application (ANDA) received for review on DATE (RECEIVED) ACCEPTABLE FOR REVIEW, submitted under section 505(j) of the Federal Food, Drug, and Cosmetic Act for TRADE NAME (IF GIVEN), (ESTABLISHED NAME) DOSAGE FORM AND STRENGTH(S).

FOR COMPLEX MRCMS ONLY:

In accordance with the Generic Drug User Fee Amendments Reauthorization of 2017 (GDUFA II), a mid-review-cycle meeting is held with applicants that have participated in the pre-ANDA program for complex generic drug products.

FOR CGT MRCMS ONLY:

In accordance with Guidance for Industry, Competitive Generic Therapies (February 2019), FDA may offer a mid-review-cycle meeting to an applicant of an ANDA for a drug designated as a CGT during the first review cycle.

The teleconference is scheduled as follows:

Date:	DATE
Time:	TIME
Phone Arrangements:	CALL-IN NUMBER AND ACCESS CODE

Agenda items will be sent to the applicant no later than seven calendar days prior to the mid-review-cycle meeting.

Meeting Agenda

Agenda

- Issued no later than 7 days before MRCM
- Provide review status update
- MRCM generally limited to discussion items listed in the agenda

Meeting Agenda

ANDA #######

MID-REVIEW-CYCLE MEETING
MEETING AGENDA

APPLICANT NAME
APPLICANT ADDRESS
Attention: CONTACT NAME
CONTACT TITLE

Dear Sir or Madam:

This is in reference to your abbreviated new drug application (ANDA) received for review on DATE (RECEIVED) ACCEPTABLE FOR, submitted under section 505(j) of the Federal Food, Drug, and Cosmetic Act for (ESTABLISHED NAME) DOSAGE FORM AND STRENGTH(S).

We also refer to the mid-review-cycle meeting to be held between the applicant and the FDA on TELECONFERENCE DATE. The purpose of the meeting is to provide review status updates and discuss Agency-selected deficiencies identified by the midpoint of the first cycle review of your qualifying generic drug product. A copy of the agenda for the meeting is enclosed for your information.

How MRCMs are Conducted

Conducting the MRCM

Discussion is generally limited to the agenda items sent by FDA to the applicant

Clarifying questions pertaining to agenda items may be submitted for Agency consideration prior to the MRCM.

Ad hoc clarifying questions

FDA will determine the appropriateness of responding during the telephone conference.

Limited to 30 minutes

Rescheduling or Canceling MRCM

Rescheduling

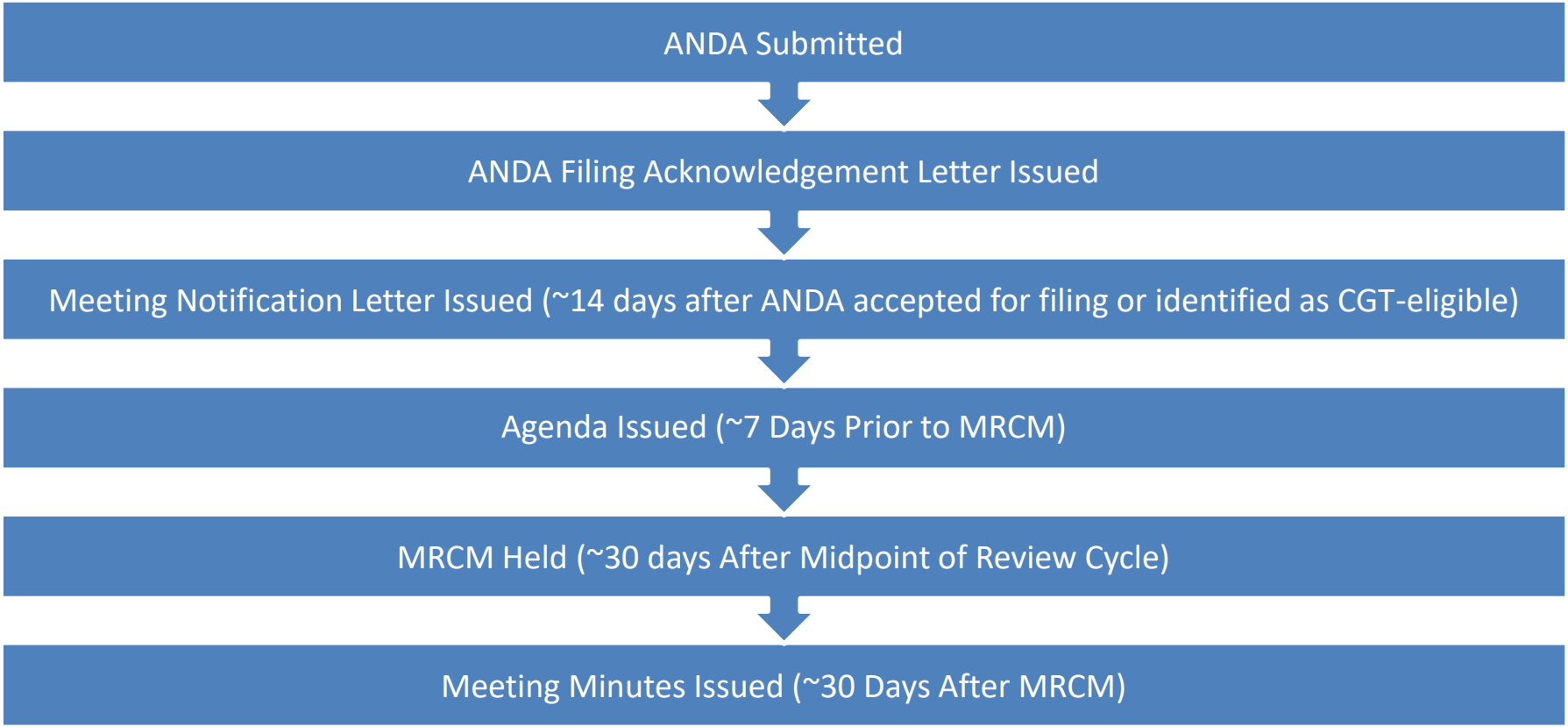
An MRCM may be rescheduled at FDA's discretion if additional information is needed from the applicant before the MRCM, if there is an unsolicited amendment that changes the generic drug user fee goal date, or if unforeseen circumstances arise.

Meeting Cancellation

- Applicants may choose to cancel the MRCM (via Administrative Amendment)
- Please provide as much notice as possible

MRCM Timeline Summary

MRCM Timeline Summary



Tips

- If applicable, identify pertinent pre-ANDA Meetings on Original Application (Sequence 0001) Cover Letter
- Contact the Regulatory Project Manager (RPM) if MRCM Meeting Notification letter has not been received within 3 weeks of Filing Acknowledgement
- Submit agenda-related clarifying questions through electronic submission gateway (ESG) and send courtesy copy to RPM
- Ensure appropriate representatives attend meeting on time
- Submit cancellation requests through ESG and send courtesy copy to RPM

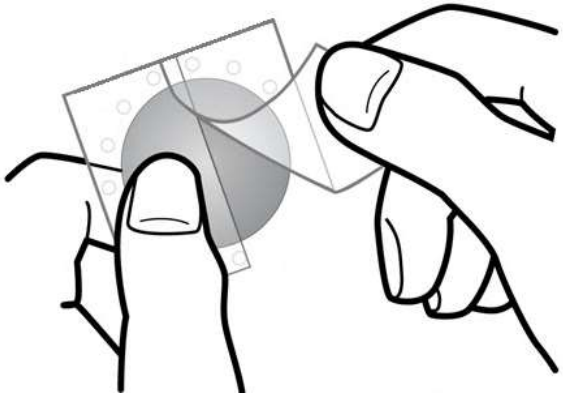
MRCM Performance

MRCMs By the Numbers

	FY18	FY19	FY20
Complex MRCMs	5	10	21
CGT MRCMs	0	2	15

*as of March 8, 2021

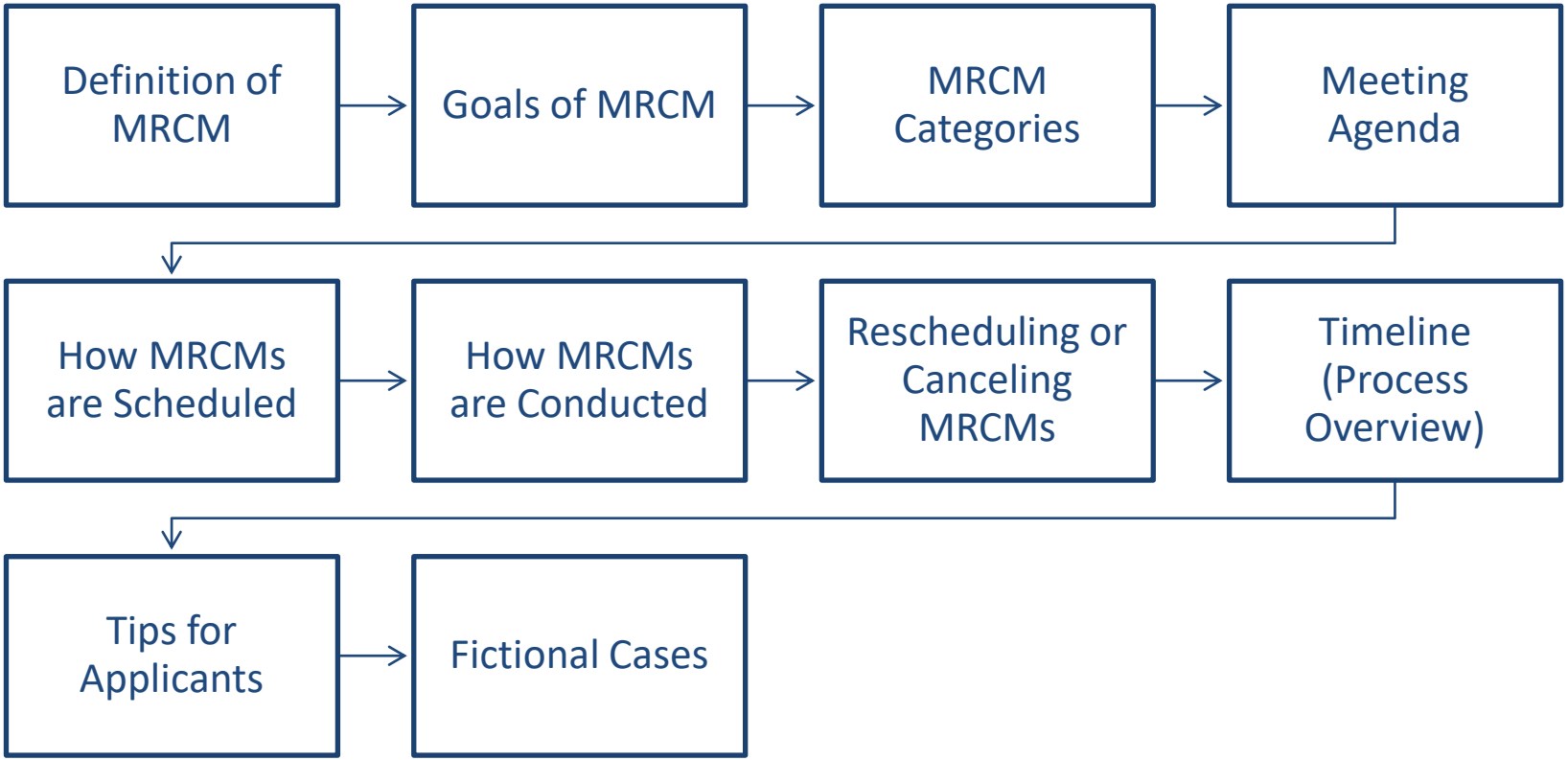
Fictional Examples of MRCM Discussions



- Patch – discussion regarding difference in product shape from the reference listed drug

- Metered Dose Inhaler – discussion surrounding alternative bioequivalence approach

Summary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Points of Contact for Assistance

For questions, please contact the Regulatory Project Manager assigned to your respective ANDA

Challenge Question #1

Who can cancel a mid-review cycle meeting?

a) The Applicant
b) The FDA
c) Either the Applicant, or the FDA
d) Neither the Applicant nor the FDA

Challenge Question #2

Under what circumstance(s) may an MRCM be rescheduled?

a) If additional information is needed from the Applicant before the MRCM
b) If an unsolicited amendment changes the goal date
c) If unforeseen circumstances arise
d) Only A and B
e) All of the above

Resources

GDUFA II COMMITMENT LETTER

GUIDANCE FOR INDUSTRY: FORMAL MEETINGS BETWEEN FDA AND ANDA APPLICANTS OF COMPLEX PRODUCTS UNDER GDUFA

GUIDANCE FOR INDUSTRY: COMPETITIVE GENERIC THERAPIES


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