GDUFA III Enhancement: Assessment of Solicited DMF Amendments

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Overview

- To describe how the GDUFA III enhancement for assessment of solicited DMF amendments can improve the ANDA assessment process

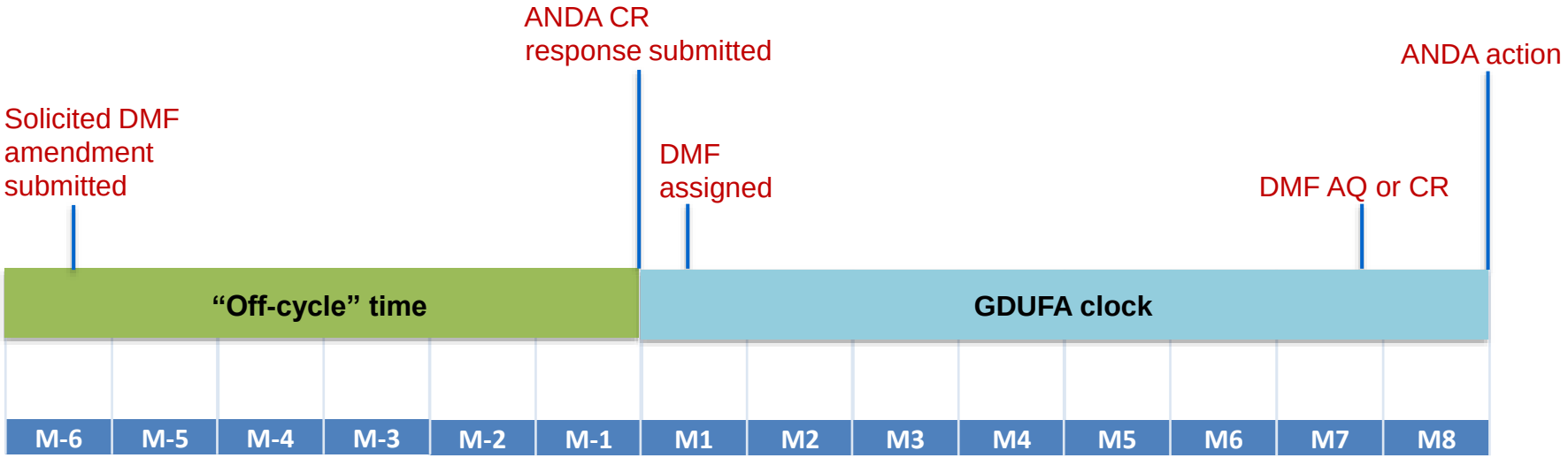
- To discuss what's new and what's changed under GDUFA III

- To enhance industry understanding of FDA's process for assessing solicited Type II DMF amendments

Background

Under GDUFA I & II, solicited DMF amendments are not picked up for assessment when there is no open review cycle for an associated original ANDA, ANDA amendment, or ANDA Prior Approval Supplement (PAS). These amendments are often referred to as “off-cycle”.

Background



GDUFA I & II Timeline Example

Background

- For an ANDA application to be approved within the GDUFA goal date, the DMF must be found adequate

- The problem is, only a small percentage (~4% in 2021) of original DMFs are found adequate after the first cycle of review

- Additionally, almost half (~44% in 2021) of the responses to DMF deficiencies are not assessed as adequate

What's New/Changed for GDUFA III

F. FDA Assessment of Solicited DMF Amendments

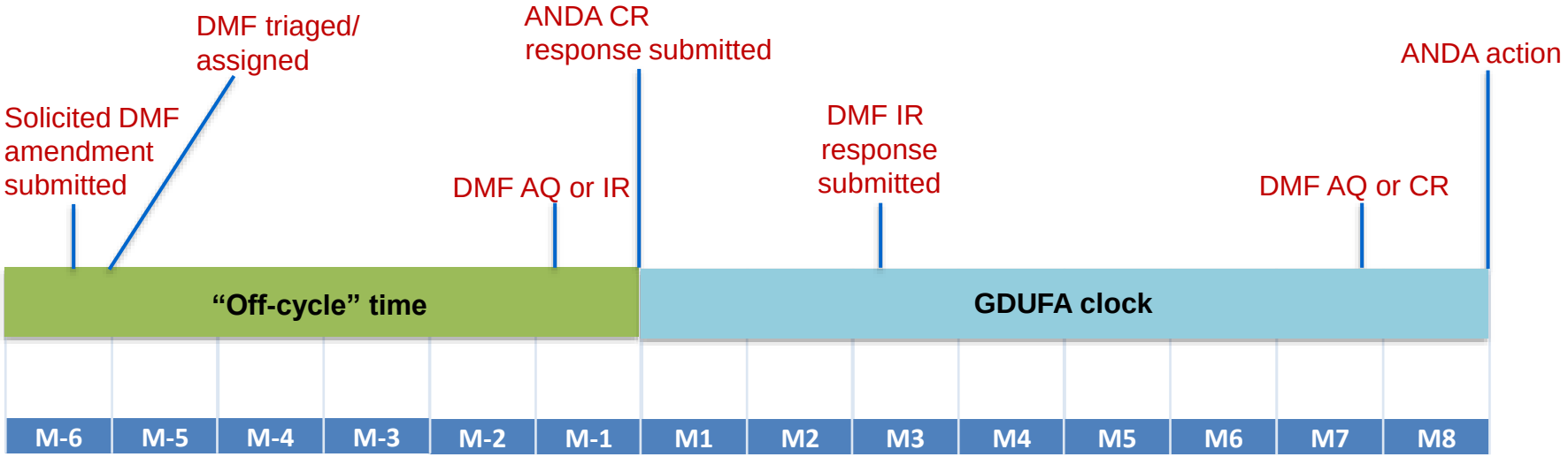
1. FDA will assess solicited DMF amendments related to original ANDAs and PASs upon receipt even if the original ANDA or PAS in which the DMF is referenced is not currently under assessment.
2. Such assessments will be conducted based on the assessment status of the DMF and other disciplines in the related ANDAs, with priority being given to those amendments related to ANDAs for which acceptability of the DMF assessment may result in an approval.

What's New/Changed for GDUFA III

- Have an opportunity to do earlier assessment and leverage "off-cycle" time to get the DMF to an adequate status sooner

- By assessing the solicited DMF amendments upon submission rather than waiting for an application assessment cycle to open, the goal is to reduce the number of cycles and total time to ANDA approval

What's New/Changed for GDUFA III



Important: Notification of response to DMFOGD mailbox

GDUFA III Timeline Example

FDA Process

- Applies to the product quality drug substance assessment discipline and its associated consults
- Does not apply to the microbiology assessment discipline
- If there is more than one associated referencing application, then each application will be considered to determine the priority for the solicited DMF amendment

FDA Process

- FDA will inform DMF holder or authorized agent of DMF Target Date (DTD) via email if the solicited DMF amendment is assigned for assessment “off-cycle”

Example of communication:

DMF AGENT NAME,

We acknowledge the receipt of your amendment to the Drug Master File (DMF) #xxxxxx received on [DMF AMENDMENT RECEIPT DATE]. The DMF amendment is currently being assessed by the FDA. According to provision VI.F. in the GDUFA III Commitment Letter, the expected completion date will be on or about [DTD]. Please note that the expected completion date is subject to change pursuant to the start of a new assessment cycle of the referencing marketing application.

Please note that submission of an unsolicited amendment may result in an extension of expected completion date. Therefore, to facilitate completion of the DMF assessment, please limit the submission of unsolicited amendments to the DMF while the amendment is being assessed.

Thank you,

DMF Team

FDA Process

- If an associated referencing application opens a new assessment cycle with a goal date requiring an earlier DTD, then the DMF amendment and associated consult(s) will have their due date adjusted to the earlier date
- If an associated referencing application opens a new assessment cycle with a goal date that would result in a later DTD, then the DMF amendment will retain the current DTD as assigned

FDA Process

- To facilitate completion of the DMF assessment, the submission of unsolicited amendments to the DMF should be limited while the amendment is being assessed

- Solicited DMF amendments deferred for assessment from an open ANDA review cycle will also be assessed for priority under this process

Thank you!

Resources

- GDUFA III Drug Master File (DMF) Review Enhancements
- GDUFA III Reauthorization