

GDUFA III Prior Assessment Process: Presumptive Q & A

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Question #1

The draft guidance states the GDUFA DMF fee needs to be paid for FDA to grant a Prior Assessment request. Does the DMF also need to be “Available for Reference”?

Answer #1



No, the DMF need not appear on the “Available for Reference” list in order for FDA to grant a DMF Prior Assessment. Please note that a pending Completeness Assessment (CA) will be processed as an Administrative CA (complete) at the time the Prior Assessment is granted and assigned.



Question #2

We plan to submit the drug substance information directly in our application rather than reference a DMF. How can we get a Prior Assessment?

Answer #2



Prior Assessment is not available when a DMF is not referenced for the drug substance information. In this case, the applicant would need to change their submission strategy and file the information in a DMF to be eligible for a Prior Assessment.

Question #3



The draft guidance states that requests for Prior assessment should be submitted to the DMF six months ahead of the planned submission date for the application. Can we submit the request *more than six* months prior to the planned submission date for the application? What happens if we submit with less than six months?

Answer #3



Yes, the DMF holder can submit the request more than six months in advance of the planned application submission and FDA will make a grant or deny determination at the time it is received. Please note that the assigned DMF review target date (DTD) for completion of the assessment will be based on the planned application submission date in the request.

Answer #3 (continued)

If the request has a planned application submission date less than six months from the receipt of the request it will be denied unless qualified for a waiver.

Question #4

The draft guidance states that for drug shortage or products that could help address a public health emergency the condition that prior requests be submitted to the DMF at least six months prior to application submission can be waived. How can I make such a waiver request and how will the DTD be set if the waiver is granted?

Answer #4



To request a waiver of the six-month condition, ensure that the cover letter of the prior assessment request clearly states that a waiver is desired. Also, make sure that drug shortage or public health emergency is clearly indicated as a qualifying factor.

Answer #4 (continued)

When a six-month waiver is granted, and you have provided at least three months of lead time before the planned ANDA submission, the DTD will typically be set to the planned submission date indicated in your request. If less than three months of lead time is given, then FDA will set a DTD consistent with available resources which may extend beyond the planned submission date indicated in your request.



Question #5

Once a DMF Prior Assessment is granted and the DTD is communicated to the holder, can that date ever change?

Answer #5



Yes, there are couple of situations that could cause a change in the DTD.

1. Unsolicited amendments to the DMF received after the granting of the prior assessment can cause an extension of the DTD. The length of the extension will be determined based on the timing and the content of the DMF amendment.

Answer #5 (continued)



2. An application submission opens a review cycle that necessitates an *earlier* DTD to meet a goal date. In this case the DMF assessment would finish earlier than indicated in our grant communication. Note that FDA would only adjust the DTD in this circumstance when it resulted in an earlier date.

Question #6

My DMF references two secondary DMFs for intermediates. Will both be assessed if a prior assessment request is granted or will these DMFs require their own request for prior assessment?

Answer #6

The draft guidance states, “any secondary DMFs referenced by a primary DMF that is granted prior assessment will be assessed during the DMF prior assessment period.” This means all secondary DMFs properly referenced by the primary DMF granted prior assessment will be covered concurrently to meet the same DTD. No separate request for a secondary DMF is needed.

Question #7

What if the applicant cannot submit the ANDA application by the date indicated in the prior assessment request?

Answer #7



As soon as you are aware that there may be a delay or the submission might not come in, please email the DMFOGD mailbox (DMFOGD@FDA.HHS.GOV).



Resources

- GDUFA III Commitment Letter: <https://www.fda.gov/media/153631/download>
- Review of Drug Master Files in Advance of Certain ANDA Submissions Under GDUFA, Guidance for Industry, Draft Guidance: <https://www.fda.gov/media/162019/download>
- GDUFA II Drug Master Files (DMFs): <https://www.fda.gov/drugs/forms-submission-requirements/gdufa-ii-drug-master-files-dmfs>
- GDUFA III Drug Master File (DMF) Review Enhancements: <https://www.fda.gov/industry/generic-drug-user-fee-amendments/gdufa-iii-drug-master-file-dmf-review-enhancements>

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