# Introducing the DMF Enhancements in the GDUFA III Commitment letter

***Jayani Perera – Chemist***

*Division of Lifecycle API (DLAPI)*
*Office of New Drug Products*
*Office of Pharmaceutical Quality, FDA/CDER*

**SBIA DMF Workshop: GDUFA III Enhancements and Structured Data Submissions**

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# GDUFA III Enhancements

**DMF Assessment Program Enhancements**

**DMF review prior to ANDA submission**:

The DMF holder would provide a "request for review" 6 months prior to the original ANDA's planned submission date for applications that meet one of the following criteria: All patents and exclusivities will expire within 12 months of the planned submission date, no more than 3 approved ANDAs, drug shortage, public health emergency, or sole source product. The "request for review" process is available to newly submitted DMFs, and previously unreviewed DMFs that will be referenced in an original ANDA to be submitted in 6 months. A DMF holder can also submit a "request for review" for a PAS to add a new API source, provided the product is related to drug shortage or public health emergency.

**Assessment of DMF solicited off-cycle 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.

Link to GDUFA III Commitment letter: https://www.fda.gov/media/153631/download

# Thinking behind the two GIII enhancements

- Aimed at enhancing first cycle approvals and reducing the number of cycles to approval
- Under GDUFA I and II, DMFs are not picked up for review unless there is a marketing application referencing the DMF
- For an ANDA application to be approved within the clock, 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 deficiencies are not assessed as adequate

# Thinking behind the two GIII enhancements Cont.

**Solution:**

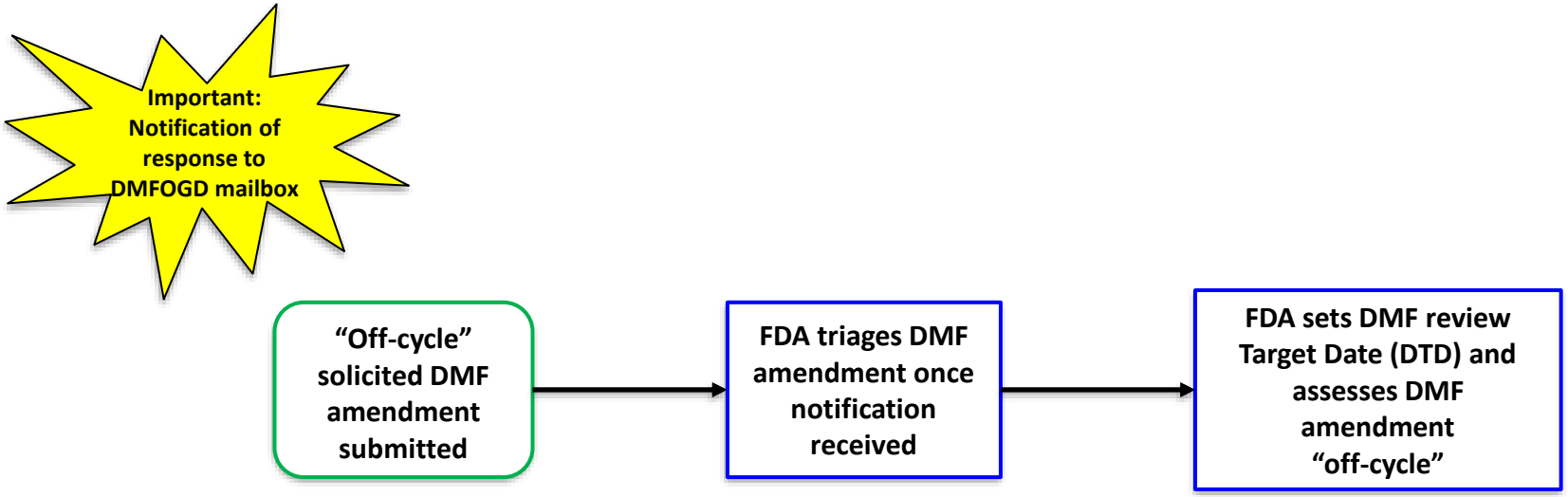
- DMFs are unique since they are separate from the application, so can be evaluated outside of an application
- Gives an opportunity to do prior assessments and solicited “off-cycle” reviews

# Specific information about each GIII enhancement

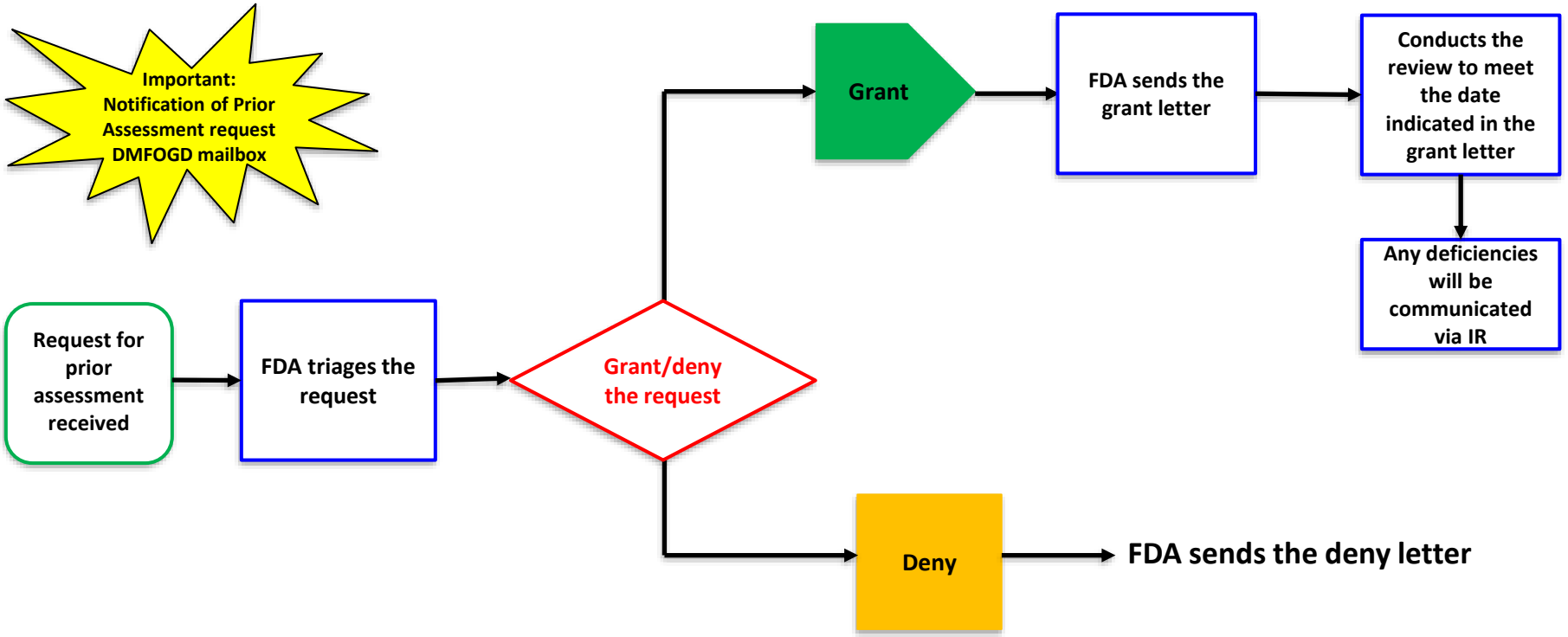
These are targeted enhancements:

- We estimate about 80-100 original DMFs might be qualified under the Prior Assessment enhancement each year
- We estimate about 50% of solicited off-cycle amendments will be picked up for review under the Solicited Off-cycle enhancement

# High Level Implementation Process: Solicited Off-Cycle Review



# High Level Implementation Process: DMF Prior Assessment



# What is to come

- GDUFA III Enhancements - Assessment of Solicited DMF Amendments: *Jennifer Nguyen*
- GDUFA III DMF Prior Assessments: Explanation and Overview*: Erin Skoda*
- GDUFA III Enhancements - DMF Prior Assessments: *Jayani Perera*
- GDUFA III DMF Review Prior to ANDA Submission: Eligibility Criteria for the ANDA Submissions: *Iain Margand*
- GDUFA III Prior Assessment Process: Presumptive Q & A: *Jayani Perera*

# 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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**Thank you!**

# Questions?