GDUFA II Drug Master File Update

Erin Skoda
Quality Assessment Lead (Acting)
Division of Lifecycle API
Office of New Drug Products
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

Drug Master Files (DMFs): What Is New?

- New Performance Goals
- Review Program Enhancements

Performance Goals: What Does It Mean?

- DMF Completeness Assessment (CA) initial review
  - 90% of Type II API DMFs complete within 60 days of the later of the date of DMF submission or DMF fee payment
  - CA process moved to the CDER Informatics Platform (the platform)

Performance Goals: What Is the Impact?

- Industry and FDA know when to expect a completeness assessment review to be finished

Performance Goals: What Can Industry Do To Assist?

- Completeness Assessments (CA):
  - Start the CA process at least 6 months in advance of a referencing ANDA

Review Program Enhancements: What Is New?

- Communication of DMF Review Comments
- Teleconferences to Clarify DMF First Cycle Review Deficiencies
- DMF First Adequate Letters
- DMF No Further Comments Letters
- Guidance on Post-Approval Changes to Drug Substances

Review Program Enhancements: What Is the Impact?

- Increased Communication between FDA and Industry
  - Improvements in Existing Communications
  - New Communications Implemented

Comment Communication Alignment: What Does It Mean?

- DMF review comments issued in parallel with the review comments relating to the DMF for the ANDA
  - Applies to comments issued to the applicant in any ANDA Complete Response Letter (CRL) and comments issued in the first Information Request (IR) letter by the drug product review discipline
  - DMFs fully migrated into the Platform

Comment Communication Alignment: What Can Industry Do To Assist?

So that the DMF review process can continue, aim to respond to:

- DMF Complete Response Letters within 30 calendar days
- Easily Correctible Deficiencies Letters within 10 business days

Teleconference Update: What Does It Mean?

Teleconferences to Clarify DMF First Cycle Review Deficiencies:

- DMF holders have 20 business days from issuance of the first cycle deficiency letter to submit a request
- FDA strives to grant or deny within 30 calendar days
- DMF holders may request an email exchange with FDA in lieu of the teleconference

Teleconference Update: What Can Industry Do To Assist?

- Request teleconferences or email exchanges only for information pertaining to clarifying issues in the first cycle review letter
- Make requests within 20 business days of the letter
- Email exchanges can be requested from: DMFOGD@fda.hhs.gov

DMF “No Further Comments” Letters (NFC) Update: What Does It Mean?

- Proceeds as in GDUFA I
- This process was migrated into the Platform in February 2017 to streamline the process
- In GDUFA II the default communication method for the NFC letter will be email

"No Further Comments" Letters (NFC) Update: What Can Industry Do To Assist?

- Obtain a secure email address by contacting: SecureEmail@fda.hhs.gov

DMF First Adequate Letters: What Does It Mean?

- New communication
- DMF holder is informed when DMF becomes adequate for the first time and there are no open issues related to review of the referencing ANDA

DMF First Adequate Letters: What Is the Impact?

- Facilitate communication between the DMF holder and the ANDA applicant to prevent late-cycle unsolicited updates to the DMF that are disruptive to the ANDA approval process

Guidance on Post-Approval Changes for Drug Substance: What Does It Mean?

- Draft guidance for industry will provide the expectations for updates to a DMF after the DMF is found adequate
- Will include data and information submission requirements for DMF holders and referencing ANDAs

Resources

- FDA Drug Master File Page
  - https://www.fda.gov/drugs/developmentapprovalprocess/formssubmissionrequirements/drugmasterfilesdmfs/default.htm
- GDUFA II Commitment Letter
  - https://www.fda.gov/downloads/forindustry/userfees/genericdruguserfees/ucm525234.pdf
- Guidance for Completeness Assessments for Type II DMFs Under GDUFA
  - https://www.fda.gov/downloads/drugs/guidances/ucm321884.pdf
- Generic Drug User Fee Amendments Activities Page
  - https://www.fda.gov/ForIndustry/UserFees/GenericDrugUserFees/ucm559570.htm


FDA
U.S. FOOD & DRUG
ADMINISTRATION