SBIA Generic Drugs Forum 2024

Policy Accomplishments

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Types of GDUFA Policy Documents

- *Guidances for Industry*
  - Describe the Agency's current thinking on a particular subject
  - Contain nonbinding recommendations
- *MAPPs ("Manuals of Policies and Procedures")*
  - Describe internal CDER policies and procedures
  - Made available to the public to increase transparency

GDUFA Policy Development

- GDUFA commitments
  - Section IX of the GDUFA III Commitment Letter
- Existing GDUFA II policy documents
- New GDUFA III program areas or enhancements
- Lessons learned from GDUFA II

Challenge Question

- You can make comments to a guidance docket at any time: True / False

Policy Documents: Performance Goals

- Docket: *Soliciting Public Comment on Appendix A of FDA's July 2018 Guidance Entitled ANDA Submissions – Amendments to ANDAs Under GDUFA* (August 2022)
- Guidance: *ANDA Submissions – Prior Approval Supplements Under GDUFA* (October 2022)
- Guidance: *Failure to Respond to an ANDA Complete Response Letter Within the Regulatory Timeframe* (December 2022)

Policy Documents: Program Enhancements

- Guidance: *Post-Complete Response Letter Clarification Teleconferences Between FDA and ANDA Applicants Under GDUFA* (October 2022)
- Guidance: *Information Requests and Discipline Review Letters Under GDUFA* (October 2022)
- MAPP: *Issuance of Information Requests and/or Discipline Review Letters for ANDAs* (October 2022)
- MAPP: *Communicating ANDA Review Status Updates with Industry* (October 2022)
- MAPP: *ANDA Suitability Petitions* (September 2023)

Policy Documents: Program Enhancements (cont.)

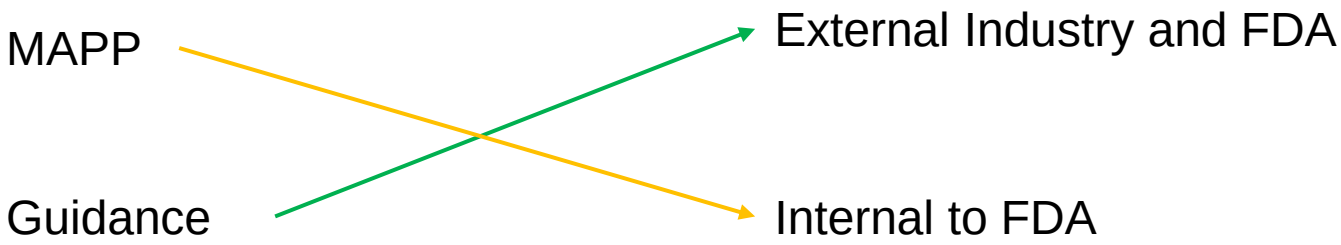
- Guidance: *Cover Letter Attachments for Controlled Correspondences and ANDA Submissions* (June 2023)
- Guidance: *ANDA Submissions – Amendments and Requests for Final Approval to Tentatively Approved ANDAs* (January 2024)
- Guidance: *Requests for Reconsideration at the Division Level Under GDUFA* (January 2024)
- Guidance: *Post-Warning Letter Meetings Under GDUFA* (September 2023)

Policy Documents: Pre-ANDA Program

- Guidance: *Competitive Generic Therapies* (October 2022)
- Guidance: *Formal Meetings Between FDA and ANDA Applicants of Complex Products Under GDUFA* (October 2022)
- MAPP: *Evaluating Requests for and Conducting Product Development and Pre-Submission Pre-ANDA Meetings* (October 2022)
- Guidance: *Controlled Correspondence Related to Generic Drug Development* (December 2022)
- Guidance: *Product-Specific Guidance Meetings Between FDA and ANDA Applicants Under GDUFA* (February 2023)
- Guidance: Controlled Correspondence Related to Generic Drug Development (March 2024)

Challenge Question

- Which policy document type is internal vs. external?



Policy Documents: DMFs

- Guidance: *Review of Drug Master Files in Advance of Certain ANDA Submissions under GDUFA* (October 2022)

Policy Documents: Facilities

- Guidance: *Facility Readiness: Goal Date Decisions Under GDUFA* (October 2022)
- Guidance: *ANDAs: Pre-Submission of Facility Information Related to Prioritized Generic Drug Applications* (December 2022)
- MAPP: *Assessment of Facility-Based Deficiency Major-to-Minor Reclassification Requests* (June 2023)
- Guidance: *Post-Warning Letter Meetings Under GDUFA* (September 2023)

Policy Documents: User Fees

- Guidance: *Assessing User Fees Under the Generic Drug User Fee Amendments of 2022* (June 2023)

Forthcoming GDUFA Policy Documents

- GDUFA III commitments
- GDUFA III draft guidances
- CDER Guidance Agenda

Challenge Question

- Where can you find out what guidance documents CDER is currently working on?

CDER Guidance Agenda updated January 2024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