Good ANDA Submission and Assessment Practices

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Agenda

- *Good ANDA Submission Practices* draft guidance for industry
- *Good ANDA Assessment Practices* Manual of Policies and Procedures (MAPP)

Drug Competition Action Plan

- Announced in 2017
- Multi-step plan to increase market competition and facilitate entry of lower-cost alternatives
- One component is to streamline ANDA submission and review
  - *Good ANDA Submission Practices* draft guidance for industry
  - *Good ANDA Assessment Practices* MAPP

Guidance and MAPP

- The guidance will help applicants avoid common deficiencies that lead to multiple review cycles
- The MAPP makes OGD and OPQ's ANDA assessment process more efficient and effective

Good ANDA Submission Practices

- Describes common, recurring deficiencies that may lead to a delay in ANDA approval
  - Limited to deficiencies identified during substantive review
- Makes recommendations on how to avoid these deficiencies
- Identifies relevant regulations and guidances

Good ANDA Submission Practices

- Patents and exclusivities
- Labeling
- Product quality
  - Drug substance
  - Drug product
  - In vitro dissolution
  - Facilities
  - Commercial manufacturing process
  - Microbiology
- Bioequivalence

Good ANDA Submission Practices

- Does not list all deficiencies identified during ANDA assessment
- It is an applicant's responsibility to submit a high-quality, complete application that FDA can approve in the first review cycle

Next Steps

- Posted in the Federal Register on January 4, 2018
  - Docket number: FDA-2017-D-6854-0001
- 60-day comment period closed on March 5, 2018
- FDA is reviewing comments

Good ANDA Assessment Practices

- Assessors should use templates and assessment tools to focus on critical attributes of the application
- Clarifies roles and responsibilities to reduce duplicative work
- OGD and OPQ will clearly communicate what deficiencies must be corrected for approval

Good ANDA Assessment Practices

- Will enable high-quality re-submissions and reduce the number of subsequent review cycles
- Can be viewed on FDA's MAPP website
  - MAPP 5241.3

Key Points

- Applicants should review the *Good ANDA Submission Practices* draft guidance
- FDA is also taking steps to enhance the efficiency of our ANDA assessment process
- Both actions aim to reduce the number of review cycles to approval

Software Support for Assessors

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Overview

- To describe how we are incorporating software into our assessments

- To explain how these tools will benefit the public and industry

Developing Tools to Support Assessors

- What information sources are used to evaluate an application? For example:
  - Databases
  - Information supplied by applicants
  - Experience with the drug product
  - Policy documents
- How does the assessor use the information?

Incorporating Software into Assessments

- Populate information in discipline templates
- Extract information from an abbreviated new drug application (ANDA) submission
- Integrate information from multiple databases
- Establish connections across related products

Impact on Public and Industry

- Greater consistency
- Timeliness
- Prioritize assessor time

Closing

- How are we incorporating software into our assessment processes?
  - Assembling and presenting information
- How will these tools benefit the public and industry?
  - Support efforts to increase first cycle approvals
  - Reduce time to approval actions when criteria are met


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