U.S. Food and Drug Administration

Generic Drug User Fee Amendments of 2012

http://www.fda.gov/gdufa

Overview:
Draft Guidance for Industry
ANDA Submissions - Content and Format of Abbreviated New Drug Applications

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Draft Guidance: Impact of GDUFA

- GDUFA enacted to speed the delivery of safe and effective generic drugs to the public and reduce costs to industry

- FDA committed to performance metrics for review of new ANDAs submitted electronically following the electronic CTD (eCTD) format
  - See GDUFA Commitment Letter available at http://www.fda.gov/downloads/ForIndustry/UserFees/GenericDrugUserFees/UCM282505.pdf

- This guidance is intended to assist ANDA applicants in improving the quality of submissions to increase the number of original ANDAs acknowledged for receipt upon initial submission and decrease the number of review cycles

Draft Guidance: Purpose and Goals

- Assists applicants in preparing ANDAs for submission to FDA under section 505(j) of the FD&C Act

- Details information to be provided in each section of the Common Technical Document (CTD) format

- Identifies the information an applicant should include to ensure that a **complete, high-quality application** is submitted

Draft Guidance: Purpose and Goals

- Comprehensive, instructive guidance on developing the content and format for ANDAs

- Compiles information an ANDA applicant needs to develop and submit a high-quality original application in one guidance

  - Guidances (30+ references)

  - MAPPs used by reviewers

Deficiencies and Industry Concerns

- The draft guidance is an opportunity for OGD to address:
  - Common deficiencies noted by reviewers
  - Common concerns about the application process voiced by industry
  - Questions frequently asked by applicants

Deficiencies and Industry Concerns

- Concern:
  - Applicants follow the ANDA Filing Checklist but frequently need more information and assistance to develop the application
- ANDA Content and Format Draft Guidance:
  - Follows, yet builds on the ANDA Filing Checklist
  - Provides more detail on the information contained in each part of the ANDA so that a complete, original application is submitted

Deficiencies and Industry Concerns

- Concern:
  - Applicants fail to provide all requested information on Form 356h
- ANDA Content and Format Draft Guidance:
  - Explains what information applicants need to provide in the application form
  - Lists the sites to be included
  - Links to the instructions for Form 356h

Deficiencies and Industry Concerns

- Concern:
  - Applicants are uncertain about where references to DMF in the application are appropriate
- ANDA Content and Format Draft Guidance:
  - Specifically states when references to a DMF is inadequate or inappropriate for a particular Module folder or subfolder

Deficiencies and Industry Concerns

- Concern:
  - Applicants have difficulty navigating the FDA's website for information
- ANDA Content and Format Draft Guidance:
  - Links to the new and improved ANDA Forms and Submissions Requirements Web Page
    - Forms
    - QbR Examples
    - QOS Examples
    - Summary Tables

Draft Guidance: Content

- The guidance explains the contents of the CTD for an ANDA
- The guidance walks applicants through each Module, each Module's folders and subfolders
  - Describe the content needed for a complete review
  - Highlight references for more information (i.e., technical specifications)
  - Details what is needed for certain products

The Common Technical Document (CTD)

- Draft guidance details the information to be provided in each section of the CTD for an original ANDA

- CTD format streamlines the variability of submission requirements among ICH member states

- Only ANDAs made electronically following the eCTD format on the date of submission will be subject to the review metric goals

The Common Technical Document (CTD)

- CTD Modules
  - Module 1: Administrative information
  - Module 2: CTD summaries
  - Module 3: Quality
  - Module 4: Nonclinical study reports
  - Module 5: Clinical study reports
- ANDA Content and Format Guidance:
  - Provides information on electronic submissions and points to current guidance on the topic
  - Indicates preferred file formats for documents contained in the submission

Module 1 – Administrative Information

- Module 1 contains administrative information for applications submitted to the FDA

- ANDA Content and Format Draft Guidance:
  - Identifies required forms, information to be included, placement
  - Identifies certifications needed and where they go
  - References guidances and regulations to explain the certifications and forms needed (as applicable)

Module 2 – CTD Summaries

- Module 2 contains:
  - Quality Overall Summary (2.3) which is an overview of the CMC section
  - Clinical Summary (2.7) which contains the submission of summary data critical to the determination of bioequivalence

- ANDA Content and Format Draft Guidance:
  - Encourages QbR format for QOS
    - References example QOS-QbR outlines, QBR summaries, FAQ documents
  - Links to summary tables for 2.7

Module 3 – Quality

- Module 3 contains the CMC information necessary to support the application.

- ANDA Content and Format Draft Guidance:
  - Link between data submitted in Module 3 and summaries from Module 2
  - Outlines CMC information specific to drug substance and to drug product
  - References instructive FDA guidance, MAPPs
  - Highlights information needed for sterile products

Module 4 – Nonclinical Study Reports

- Draft guidance is silent on Module 4 as ANDAs generally do not contain data required for Module 4

Module 5 – Clinical Study Reports

- Module 5 contains all of the clinical study report data needed to support the application and demonstrate that the generic is bioequivalent to the RLD

- ANDA Content and Format Draft Guidance:
  - Link between data submitted in Module 5 and summaries in Module 2
  - References product specific guidances
  - Lists in vivo and in vitro studies that may be submitted

Questions?

- For questions regarding the draft document contact:
  - (CDER) Elizabeth Giaquinto 240-402-7930
  - (CBER) Office of Communication, Outreach, and Development, 800-835-4709 or 240-402-7800.

- Please submit any comments on the guidance or this webinar to the public docket
  - FDA-2014-D-0725
  - Electronic comments may be submitted at www.regulations.gov

Thank you!