U.S. FOOD & DRUG ADMINISTRATION

# Filing Review
# Do's and Don'ts

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# Discussion Overview

- Common deficiencies
- Best Practices
- Communications
- Resources

# Form FDA 356h

- Field 20
  - Ensure this is consistent with the patent certification provided in module 1.3.5.2
- Field 29
  - List of all facilities for the drug substance and drug product along with the contact person **at the facility**
  - Provide the type of testing conducted (if applicable)
  - Information should correspond with 3.2.S. and 3.2.P.

# Cover Letter

- Refer you to the suggested cover letter template found in Appendix B in the draft guidance for industry on *ANDA Submissions—Content and Format of Abbreviated New Drug Applications*

# Right of Reference

- Statement of right of reference for each and every DMF referenced in the application
- Should be located in module 1.4.2

# Basis of Submission

- In section 1.12.11, provide the reference listed drug (RLD) as well as the reference standard (RS), if different

# Clinical Summary Tables

- Provide tables for pivotal **and** pilot studies
- PK studies
  - Table 10
    - Should provide the location of the LTSS data **and** a hyperlink to the information
    - Provide all the analytes identified in the product specific guidance

# Clinical Summary Tables

- Ensure the correct clinical summary tables are provided for your respective study

# Tabular Listing of Studies

- Module 5.2
- List all studies – pilot and pivotal

# Batch Records

- Provide all blank manufacturing and packaging records
- Identify the commercial batch size in the blank manufacturing records
- Fully and completely translated to English*

# Impurity Tables

- Justification of Specification for drug substance and drug product
- Separate tables for:
  - Specified Identified
  - Specified Unidentified
  - Unspecified Impurities
- Fully completed table
  - If marked N/A, provide the reason

# API Lot Number

- API Lot numbers should match
  - Sample statement
  - Stability data
  - Executed batch records
  - Certificate of Analysis
- Two API lots for each strength should be used
- Controlled Correspondence

# Stability Data

- Clearly indicate stability initiation date and pull dates
  - Dates should be included within the stability tables
    - Common issue: Dates on stability records do not correspond with dates provided in a separate table
- 3 Time points, 6 months (180 days) for both Accelerated and Long Term stability studies

# Stability Data

- If accelerated studies fail:
  - Do not discontinue stability studies prior to 6 months
  - Provide failure analysis
- Container Orientation
  - Complete worst-case and non-worst-case stability data for drug products

# Reconciliation Table

- Module 3.2.R
- Table to include theoretical yield, actual yield, and packaged yield
- Should express in number of units

# Best Practices

- All documents translated to English
- All documents follow eCTD and PDF specifications
- Check for completeness

# Communications

- Questions on the status of an ANDA or Suitability Petition
  - ANDAFiling@fda.hhs.gov
- Questions not referencing a specific application
  - GenericDrugs@fda.hhs.gov

# Resources

- Draft Guidance for Industry ANDA Submissions — Content and Format of Abbreviated New Drug Applications (June 2014)
- Guidance for Industry ANDA Submissions – Refuse-to-Receive Standards (Revision 2, Dec. 2016)
- Guidance for Industry ANDA Submissions – Refuse to Receive for Lack of Justification of Impurity Limits (Aug. 2016)
- Guidance for Industry ANDAs: Stability Testing of Drug Substances and Products Questions and Answers (May 2014)
- Guidance for Industry Providing Regulatory Submission in Electronic Format – Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (Revision 3, May 2015)
- Guidance for Industry Controlled Correspondence Related to Generic Drug Development (September 2015)

# Thank You!

Please complete the session survey:

**surveymonkey.com/r/GDF-D2S02**