Outline

• Background
• General Errors
• Form 2253 Submission Errors
• Advisory/Accelerated Approval Submission Errors
• Grouped Submission Errors
• Test Submission Process
Timeline

• June 24, 2019 – FDA Published the Final Guidance titled “Providing Regulatory Submissions in Electronic and Non-Electronic Format – Promotional Labeling and Advertising Materials for Human Prescription Drugs”

• Guidance describes the structure and format for promotional submissions in eCTD format
  – Contains both Binding Requirements and Nonbinding Recommendations

• 24 months after the publication of the Final Guidance, required submissions described in the guidance must be submitted in eCTD format
  – Required submissions will be mandatory starting June 24, 2021

• Firms are not required—but are STRONGLY encouraged to—submit electronically other types of promotional material submissions
  – NOTE: Complaints should only be submitted as paper copies and cannot be accepted in eCTD
Submission Processing

- eCTD-formatted submissions facilitate automated processing of Promotional Submissions.
- Manual processing of Promotional Submissions requires greater level of effort than other submission types.
- eCTD only allows Promotional Submissions to be coded automatically when free of errors.
OPDP QC Process

• Three primary pathways for Promotional Submission Quality Control (QC)
  – Electronic Submission Gateway (ESG) Validation
  – Daily QC reports to OPDP Project Management Team
  – OPDP Document Room Manual Review

• QC reports monitor submissions for invalid Issue Date, Incomplete Submissions (missing Form, labeling, or materials), or submissions that have failed automated processing

• Document Room notifies RPM team when errors in coding are identified

• OPDP RPM will contact Sponsor when errors are identified in Promotional eCTD Submissions
General Errors
General Errors

• Incorrect Application Number
  – Promotional Materials for one product submitted to a different product
    • Submitter will need to revise and resubmit
  – Same 2253 for multiple Application Types
  – Incorrect Application Number in Cover Letter or Form 2253

• Incorrect Material Document Type Code

• Audience Type in US-regional file doesn’t match the Cover Letter or Form

• Issue Date in US-regional file improperly formatted
  – Correct format is YYYYMMDD

• Orphan files included in Submission
Submission ID

• The Submission ID field allows a submission to be linked to a previous eCTD Submission

• When submitting files that should be linked, the Submission ID field should match the previous Submission’s Sequence Number
  – Ex: The Submission ID of an Advisory Resubmission should match the Sequence Number of the Original Advisory

• Submitting an incorrect Submission ID can result in delayed processing
Form 2253 Errors
Form 2253 Errors

• Product Labeling not submitted under 1.14.6
  – Excluded or submitted under a different heading
• Materials not submitted under Section 1.15.2.1
• Including a Cover Letter under a Correspondence Heading
• Including a Form 356(h)
Advisory/Accelerated Approval Errors
Advisory/Accelerated Approval Errors

• Labeling submitted under Section 1.14
  – Single Annotated Label submitted under Section 1.14
    • Should be under 1.15.2.1.3 for each material
  – Clean copy submitted under Section 1.14.2 or 1.14.6
    • Not required

• Hyperlinks to external sites or resources

• Submitting a Withdrawal instead of a General Correspondence
  – General Correspondence should be used to notify Agency that Submitter will no longer wait for Advisory Comments and plans to disseminate materials
  – Withdrawal Heading should only be used when Materials will not be disseminated publicly
Grouped Submission Errors
Grouped Submission Errors

- Form 2253 Box 3 – “Single Product” selected when submitted as a Grouped Submission
  - “Multiple Products” box should be checked
- Application List in US-regional file doesn’t match Application List with Form 2253 or Cover letter
- PIs for all Products in Group not included
- Supplemental Application List for Form 2253 not included or placed under Cover Letter Heading
  - Should be placed under the same heading as Form 2253
Test Submission Process
Test Submissions

• Test Submission Process provides Submitters with an opportunity to validate eCTD submission structure prior to submitting to Production Environment

• Recommendation is to submit at least one of each Promotional Submission Type in Test Environment before submitting in Production

• OPDP Project Management Team will review the structure of the submission and provide feedback
  – Will provide instructions for corrections, if necessary
Test Submissions - Process

• Begin by viewing the available presentations on the OPDP eCTD webpage
  – Prepare any questions you may have for the OPDP eCTD Team
• Contact the OPDP eCTD Mailbox and send the following items:
  – Questions to be answered
  – Types of Submissions (Accelerated Approval, Advisory, 2253, etc)
  – Availability (Dates & Times) for a 30-minute meeting
• OPDP eCTD Team will schedule a planning meeting
  – Will provide answers during the meeting
  – Assist with planning test cases
• Submit Test Files
  – Notify OPDP eCTD Mailbox of results (either accepted or rejected)
  – Be sure to provide the COR ID when the file is accepted
• OPDP eCTD Team will review test submission(s) and provide feedback
A Word on Enforcements...

- Very few Companies test Response Letters:
  - Response to Notice of Violation or Warning Letter
  - Response to Letter of Inquiry
- Response Letter Submissions are not mandatory after the 24-month transition period
- Submitters are strongly encouraged to include these Submission Types in their Test Plan
Resources

- OPDP eCTD Mailbox- OPDPeCTD@fda.hhs.gov
- OPDP eCTD Webpage - www.fda.gov/OPDPeCTD
- eCTD Test Submission Instructions - https://www.fda.gov/industry/create-esg-account/setting-webtrader-account-checklist
- OPDP Electronic Submissions Guidance - https://www.fda.gov/media/128163/download
- eCTD Validation Criteria - https://www.fda.gov/media/87056/download
- Comprehensive Table of Headings – https://www.fda.gov/media/76444/download
- eCTD Submission Standards – https://www.fda.gov/media/93301/download
- eCTD Sample Submissions - https://www.fda.gov/media/83809/download