FDA's Module 1 Update: From Ideas to Implementation

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Agenda

- Why? – Advantages to FDA
- What? – Significant changes
- Who? – Impact to stakeholders
- When? – Implementation timeline
- Where? – Getting help
- Questions I can answer
- Questions I can’t answer

Advantages to FDA

- Automation
  - 46,494 Form FDA 2253 submissions to CDER OPDP in CY2014 (roughly 80,000 materials)
- Grouped submissions
  - Using grouped submissions is optional!
- Maintainability
  - Attribute code lists
- Keeping up with business
  - CTOC updates
  - Submission metadata

Significant changes

- id
  - D-U-N-S number of your corporate HQ
- submission-description (optional)
  - A high level description of the purpose of the submission
- applicant-contacts
- The cross-reference-application-number electronically provides the same information found on the 356h form
  - CROSS REFERENCES (List related License Applications, INDs, NDAs, PMAs, 510(k), IDFs, BMFs, and DMFs referenced in the current application.)
  - A cross reference only needs to be identified once
  - Does not replace the information submitted in m1.4.4

Significant changes (2)

- Removed elements
- Building regulatory activities
  - Submission-id and sequence number
- Application forms
  - What is considered an application form?

Removed elements

- Date of submission (date format)
  - Dates were often wrong – sometimes off by a day; sometimes off by years
  - FDA review tools will display the “receipt date” from our regulatory tracking system
- Product information (type and name)
  - Multiple errors for missing product information or information that has changed
- Related sequence number
  - Errors for multiple related sequence numbers or circular references
  - This concept is simplified by using submission-id and sequence-number in the new M1

Building regulatory activities

- Regulatory Activity = The entire group of submissions supporting a specific regulatory activity
  - e.g., an original application and all its amendments leading to approval
- Within each application:
  - submission-id = first sequence number for each “new” regulatory activity (change in submission-type)
  - e.g., a new efficacy supplement to an approved application is a new regulatory activity
  - Submission-id remains constant (the same) to group submissions together into their specific regulatory activity
- Sequence-number = concept is unchanged
  - Must be unique within the application
  - 4 digits
  - Start at 0001, even for presubmissions

Application forms

- 1571, 356h, 2252, and 2253
  - A single form per application
- Grouped submissions require 1 form per application referenced in the admin section of the us-regional
  - Exceptions:
    - grouped submissions to the same application – see addendum 2 on M1 website
    - grouped promotional labeling and advertising submissions
- Promotional labeling and advertising submissions do not require a 356h
  - Draft Guidance for Industry: Providing Regulatory Submissions in Electronic and Non-Electronic Format—Promotional Labeling and Advertising Materials for Human Prescription Drugs

Impact to stakeholders

- Industry
  - Opportunity for companies to develop streamlined processes to submit high volume 2253s electronically over the electronic submission gateway (ESG)
  - Challenge of maintaining unique sequence numbers if 3rd parties are involved in preparation or submission
  - Opportunity to send a single grouped submission that previously required many sequences
  - Challenge of identifying grouped submissions where all content is truly shared in the same eCTD heading location

Impact to stakeholders (2)

- FDA
  - Major updates to validation, processing, and tracking systems
  - Learning curve with updated review software
  - Electronic submission volume continues to increase

Implementation timeline

- Past
  - Testing… testing… 1… 2… 3(years?)…
- Thank you for your help in the recent pilot!
  - 7 individual sponsors/vendors and approximately 50+ sequences submitted
  - Results were sent to individuals, were used to create this presentation, and will inform future updates to specifications

Implementation timeline (2)

- Present
  - Final tweaks to systems
  - Reviewer training
- Outreach
  - DIA
  - Webinars

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Implementation timeline (3)

- Future
  - 30 days notice before the public acceptance date
  - Expected in the 3rd Quarter of FY 2015 (which ends June 30, 2015)
  - Transition to the new M1
  - Maintenance of specifications and code lists
  - The retirement date for us-regional DTD v2.01 has not been set

Implementation timeline (4)

- Using the new M1 is optional
  - If you do not need to submit promotional materials
- Using the new M1 will be necessary to submit:
  - Promotional labeling and advertising submissions to CDER OPDP
  - Grouped submissions
- After transitioning an application to the new M1, that application must continue to use the new M1
  - Do not mix DTD v3.3 and older DTD version submissions

Getting help

- esub@fda.hhs.gov
  - Yes, you can cc me
- CDER eCTD Web page
  - Guidances, specifications, and supporting files
  - Includes the new M1 documents
- CDER Electronic Submissions Presentations Web page
  - Archive of presentations including general eCTD topics

Questions I can answer

- CDER OPDP submissions
  - Do not submit a 356h form with promotional labeling and advertising submissions
  - Do not submit a cover letter in section 1.2; promotional labeling and advertising correspondence belongs in 1.15.1
    - No correspondence for 2253 submissions
  - Form 2253 should be included with draft submissions to CBER APLB, but not to CDER OPDP
  - Use life cycle if you are withdrawing materials or fixing a mistake in a previous submission
  - Reference all product labeling in 1.14.6 for grouped submissions

Questions I can answer (2)

- Grouped Submissions
  - Rejection for any reason will lead to rejection for all applications in the group
  - Submission can be “un-grouped” at any time by submitting new/changed files to a single application only
  - FDA review tools will be modified to show some grouped submission information for support and review purposes
  - Only 1 form is needed when submitting to multiple regulatory activities in a single application (see errata 2)

Questions I can answer (3)

- M1 New Specifications
  - The id element should be completed with your corporate HQ D-U-N-S #
    - Pick the corporate HQ of the sponsor/applicant if more than 1 party is submitting
    - Each establishment reported on the 356h also needs a D-U-N-S
  - A technical contact should be prepared to discuss eCTD publishing and processing issues
  - Only 1571 forms and 356h forms belong in the admin section of the us-regional (this is for your tool vendors)

Questions I can't answer

- How do we manage eCTD sequence numbers if a 3rd party will be preparing promotional labeling and advertising submissions?
  - Sorry, we can't tell you HOW to manage them. You will need to manage them as duplicate sequence numbers will be rejected.
- How do I submit xyz promotional material?
  - Start with the guidance
    - Draft Guidance for Industry: Providing Regulatory Submissions in Electronic and Non-Electronic Format—Promotional Labeling and Advertising Materials for Human Prescription Drugs

Questions I can’t answer (2)

- When will us-regional DTD v3.3 be required?
  - It will be, if you need to submit 2253 submissions
- How do I complete FDA Form XYZ?
  - There is a list of contact POCs next to each form on the FDA Forms Web page

Thank you!

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Ask