Update on Electronic Regulatory Submissions

Ginny Hussong, Acting Director
Office of Business Informatics, CDER
US Food and Drug Administration

Philadelphia, PA
11 May 2015
DIA Disclaimer

The views and opinions expressed in the following PowerPoint slides are those of the individual presenter and should not be attributed to Drug Information Association, Inc. (“DIA”), its directors, officers, employees, volunteers, members, chapters, councils, Special Interest Area Communities or affiliates, or any organization with which the presenter is employed or affiliated.

These PowerPoint slides are the intellectual property of the individual presenter and are protected under the copyright laws of the United States of America and other countries. Used by permission. All rights reserved. Drug Information Association, DIA and DIA logo are registered trademarks or trademarks of Drug Information Association Inc. All other trademarks are the property of their respective owners.
FDA Disclaimer

The views and opinions presented here represent those of the speaker and should not be considered to represent advice or guidance on behalf of the Food and Drug Administration.
Outline

• Electronic Submission Requirement
  – eCTD Final Binding Guidance
  – eCTD Technical Conformance Guide

• eCTD New Module 1 Format (DTD 3.3)

• Electronic Submissions Gateway
End of Paper

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON, D.C. 20503

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION
WASHINGTON, D.C. 20408

August 24, 2012

1.1 *By 2019, Federal agencies will manage all permanent electronic records in an electronic format*

By December 31, 2019, all permanent electronic records in Federal agencies will be managed electronically to the fullest extent possible for eventual transfer and accessioning by NARA in an electronic format. By December 31, 2013, each agency will develop and begin to implement plans to achieve this transition. Agencies should also consider the benefits of digitizing permanent records created in hard-copy format or other analog formats (e.g., microfiche, microfilm, analog video, analog audio).
Framework for Required Electronic Submissions

FDASIA Guidance
How does FDA plan to implement Section 745A(a) of the FD&C Act?

eStudy Guidance
Binding Guidance—Requires that studies are compliant with the standards outlined in the FDA Data Standards Catalog

Data Standards Catalog
Lists supported and/or required standards.

eCTD Tech Conformance Guide
Recommendations for the standardized electronic submission format of INDs, NDAs, ANDAs, BLAs, and DMFs

eCTD Guidance
24 months after guidance is finalized, content must be submitted to the Agency electronically in the format specified in the guidance.
How will eSubmissions be Implemented?

24 Months after Final Guidance

“745A(a) Umbrella” Implementation Guidance

- NDAs, ANDAs, BLAs, INDs
  - Timetable
  - Content
  - Format

Individual Guidances

Final Published December, 2014

745A(a) FD&C Act

FDASIA Guidance

How does FDA plan to implement Section 745A(a) of the FD&C Act?

Providing Regulatory Submissions in Electronic Format — Submissions Under Section 745A(a) of the Federal Food, Drug, and Cosmetic Act

Guidance for Industry

November 2014

Electronic Submissions

745A(a) Umbrella
When will eCTD Format be Required?

- **eCTD Guidance**
  - Binding Guidance requires the electronic submission of NDAs, BLAs, ANDAs, INDs, DMFs in eCTD Format

- **Published**
  - May 5, 2015

- **Required**
  - May 5, 2017

- **Compliance**
  - 24 Months*
  - Electronic submissions using the version of eCTD currently supported by FDA. As specified in the FDA Data Standards Catalog

*36 months for INDs
What Submission Types are Applicable?

FDASIA Section 745A(a) applies to Submissions under section 505(b), (i), or (j) of the FD&C Act

NDAs
ANDAs
BLAs
INDs
DMFs or BPFs
Combo products

eCTD Guidance
Binding Guidance requires the electronic submission of NDAs, BLAs, ANDAs, INDs, DMFs in eCTD Format

Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications
Guidance for Industry

Final Published
May 5, 2015
What are the eCTD Specifications?

Published May 5, 2015
# What eCTD Formats will be Required?

## FDA Data Standards Catalog v4.1 (04-09-2015) - Supported and Required Standards

This table contains a listing of the data exchange, file formats and terminology standards supported at FDA. These standards have gone through all the steps necessary to make this part of the regulatory review process, including posting of regulatory guidance documents and associated implementation guidelines and technical specifications. The submission of standardized data using any standard not listed, or to an FDA Center not listed, should be discussed with the Agency in advance. This catalog is incorporated by reference in the guidance to industry, Providing Regulatory Submissions in Electronic format—Standardized Study Data (http://www.fda.gov/downloads/Drugs/Guidances/UCM292334.pdf). A separate catalog will be published in the future that will contain a listing of standards that are in the development testing, adoption or research & development (R&D) phases.

<table>
<thead>
<tr>
<th>Use</th>
<th>Data Exchange Standard</th>
<th>Exchange Format</th>
<th>Standards Development Organization (SDO)</th>
<th>Supported Version</th>
<th>Implementation Guide Version</th>
<th>FDA Center(s)</th>
<th>Date Support Begins (MM/DD/YYYY)</th>
<th>Date Support Ends (MM/DD/YYYY)</th>
<th>Date Requirement Begins (MM/DD/YYYY)</th>
<th>Date Requirement Ends</th>
<th>Regulatory Reference and Information Sources</th>
</tr>
</thead>
</table>

http://www.fda.gov/forindustry/datastandards/studydatastandards/default.htm
How to Submit eCTD Submissions?

- Background / Purpose
- General Considerations
- Organization of eCTD (Modules 1-5)
- Issues and Solutions

eCTD Tech Conformance Guide
Recommendations for the standardized electronic submission format of INDs, NDAs, ANDAs, BLAs, and DMFs

Coming Soon!
Waivers and Exemptions

Are there **Waivers** from the Requirement?

**No.**

Are there **Exemptions** from the Requirement?

**Yes.**
Types of Submissions Exempted

- INDs for
  - Non Commercial Products
    - Investigator-sponsored INDs
    - Expanded access INDs (e.g., emergency use INDs, treatment INDs)
  - Devices Regulated by CBER

- BLAs for Devices Regulated by CBER
eCTD Guidance

Binding Guidance requires the electronic submission of NDAs, BLAs, ANDAs, INDs, DMFs in eCTD Format

Will FDA Reject non-compliant submissions?

Yes.
Must submit electronic submissions using the eCTD version currently supported by FDA.

- The version of eCTD currently supported is specified in the Data Standards Catalog.

Must obtain a pre-assigned application number by contacting the appropriate Center.

Must follow the FDA eCTD technical specification Table of Contents Headings and Hierarchy.
• **Must** adhere to the formats and versions specified in the FDA Specifications for File Format Types Using eCTD Specifications.

• **Must** adhere to the FDA Portable Document Format (PDF) Specifications.

• **Must** use the eCTD replace operation rather than submitting the file as *new* if a document replaces a document previously submitted ...
- **Must** include only FDA fillable forms (e.g., 1571 or 356h) and electronic signatures to enable automated processing of the submission. *Scanned images of FDA forms will not be accepted.*

- **Must** not submit paper copies of the application, including review & desk copies when submitting in eCTD format.

- **Must** use the FDA ESG for all submissions that are 10 gigabytes (GB) or smaller.
eCTD Technical Conformance Guide

- Includes non-binding recommendations
- Fills in the gaps missing – will update continually
- Your input/comments sought
- To be published next 1-2 months
Looking forward to a Smooth Transition

- Standardized format = more efficient review process
- No more paper
- Increased use of ESG
eCTD New Module 1 (3.3 DTD)

• FDA will accept submissions as of **JUNE 15, 2015**.
• Submit a sample in advance if desired – see the website for standard sample instructions.
• Once you convert to the 3.3 DTD you must stick with that version for all subsequent submissions within an application.
• Attend the Track 2 session on Tuesday for more info on Module 1.
• ESUB@fda.hhs.gov
Electronic Submissions Gateway

• Increase concurrent processing capability and send back acknowledgements to submitter more quickly

• Improve the capacity to handle increased submission volumes (~20-30% annually)

• Higher availability & more robust failover capabilities due to increasing volumes
2015
ESG Program Board In Process &
Planned Initiatives

• Review and update the Account set-up process.

• Renewal and maintenance of certificates.

• Review and update external communication plan.

• Review and update the ESG web pages.

• Review and update the ESG user guide.
2015
ESG Program Board In Process & Planned Initiatives

- Provide more information to submitter when receipts / acks are generated by ESG and Center

- Work with PhRMA / BIO on ESG metrics useful to industry

- Collaborate with PhRMA / BIO on industry needs for future ESG enhancements
Resources for YOU

• The Final Binding eCTD Guidance:

• The eCTD Website:

• The FDA Data Standards Catalog:

eSUB@fda.hhs.gov – General eSUB questions
eDATA@fda.hhs.gov – Clinical and non-clinical data questions