

Overview of Electronic Submissions Preparation and Tools

Crystal Allard, Director, Division of Regulatory Science Informatics (DRSI), Office of Science (OS), CTP

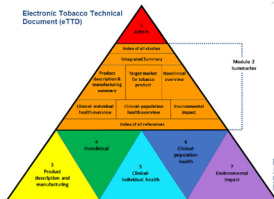
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- Grouping Products In Submissions
- Organizing Submissions, *Module By Module*
- Electronic Submission Technical Specifications
- eSubmission Preparation Tools
- eSubmission Submittal
- When to Call the Help Desk
- Additional Resources



Organization



- Grouping
- Submission Table of Contents
- Technical Specifications

Tools



- FDA eSubmitter

Modes



- CTP Portal

Background

- Health Level 7 (HL7)
- Regulated Product Submission (RPS)
- eCTD and eTTD

Multiple Products, One Submission to CTP

- If same:
 - Domestic [Manufacturer](#) or [Importer](#)
 - Submission type (PMTA, SE, etc.)
 - [Product category](#)
 - [Product subcategory](#)

GROUPING

File Home Insert Draw Page Layout Formulas Data Review View Help ACROBAT Tell me what you want to do

Cut Copy Paste Format Painter Clipboard

Calibri 11 A A B I U Font

Wrap Text Merge & Center Alignment

General \$ % , .0 .00 Number

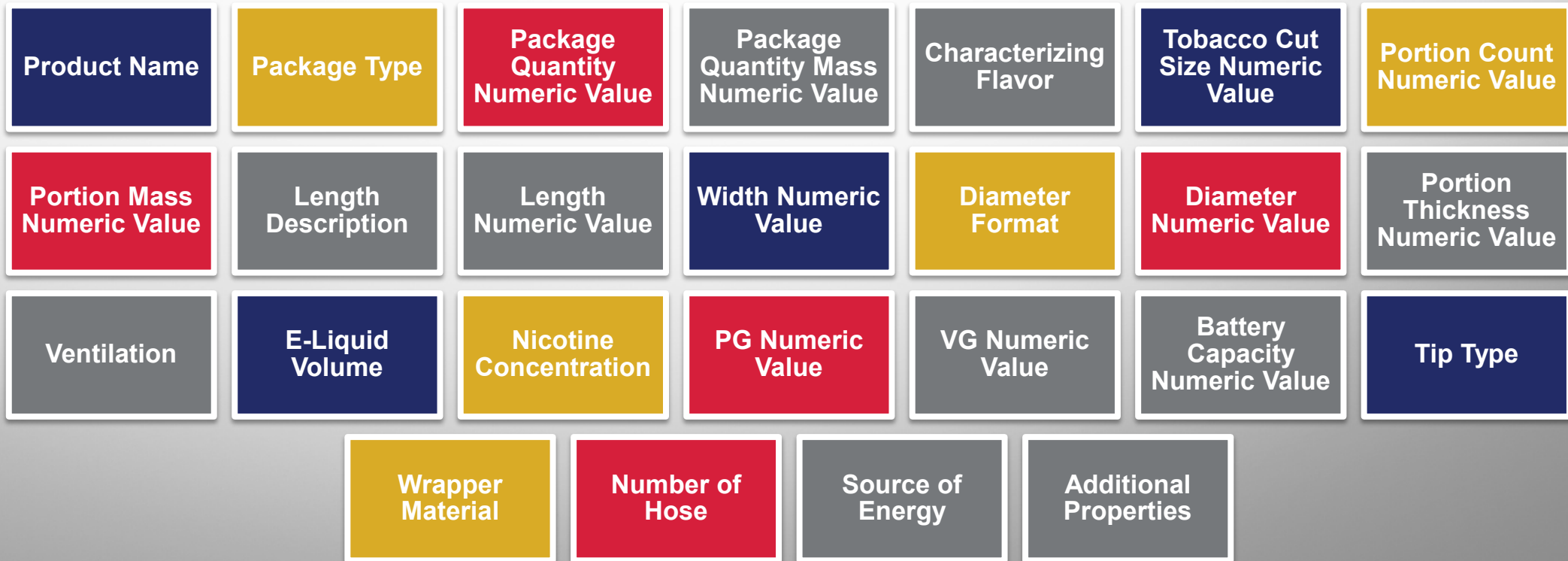
Normal Bad Good Check Cell Explanatory ... Input Styles

READ-ONLY This workbook is locked for editing by another user. Save As

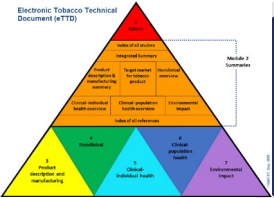
AR92

	A	B	C	D	E	F	G	H	I	J	K
1	Product Name	Package Type	Package Type, if Other	Package Quantity Numeric Value	Units (Package Quantity)	Units, if Other (Package Quantity)	Package Quantity Mass Numeric Value	Units (Package Quantity Mass)	Units, if Other (Package Quantity Mass)	Characterizing Flavor	Characterizing Flavor, If other
2											
3											
4											
5											
6											

GROUPING



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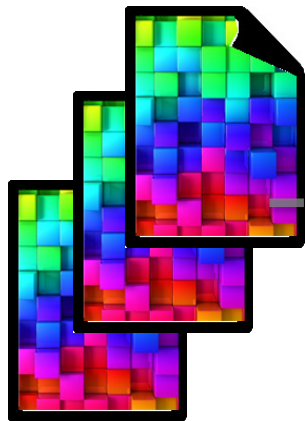
Modes



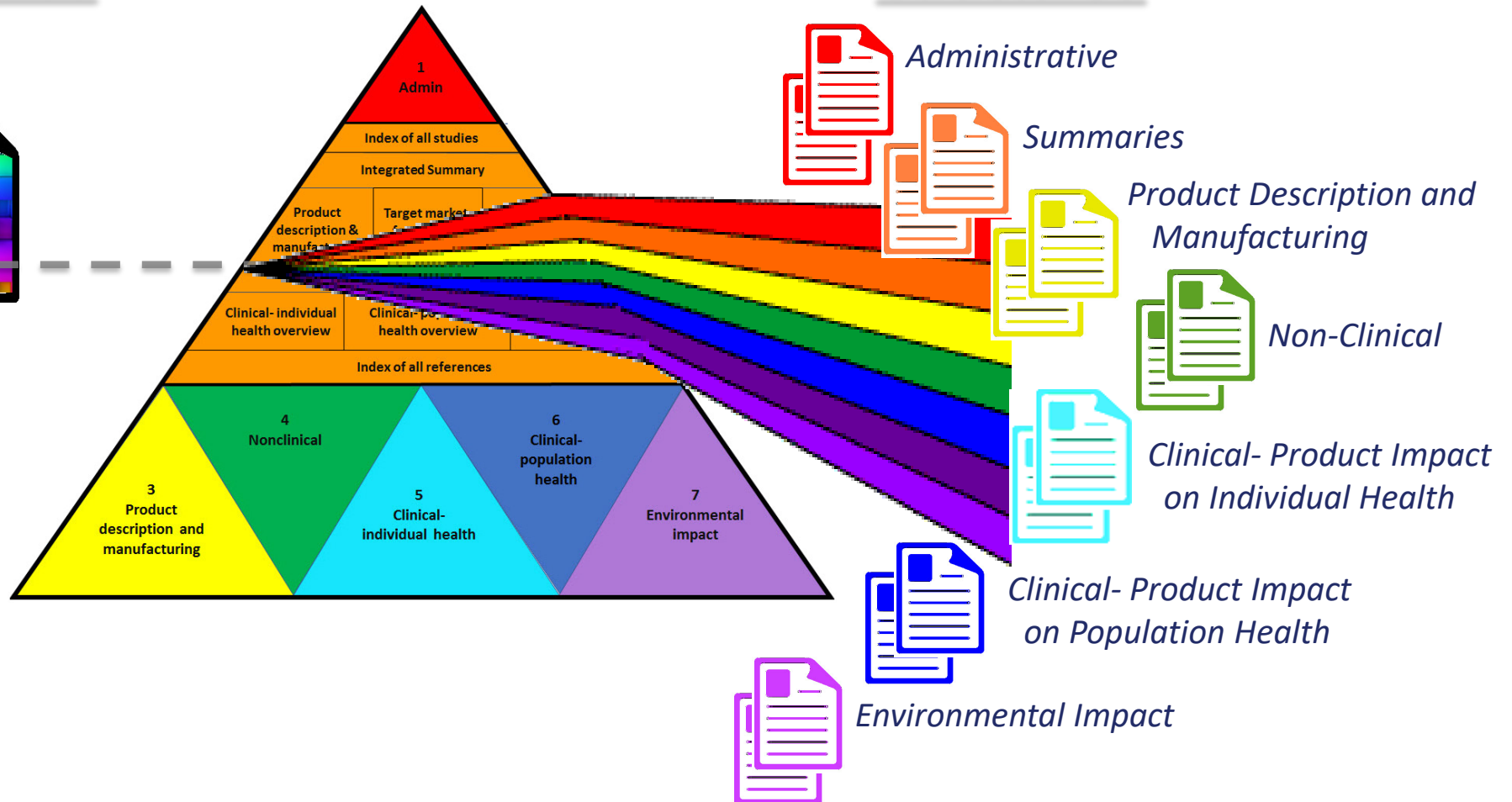
- CTP Portal

TOBACCO TECHNICAL DOCUMENT

UnStructured

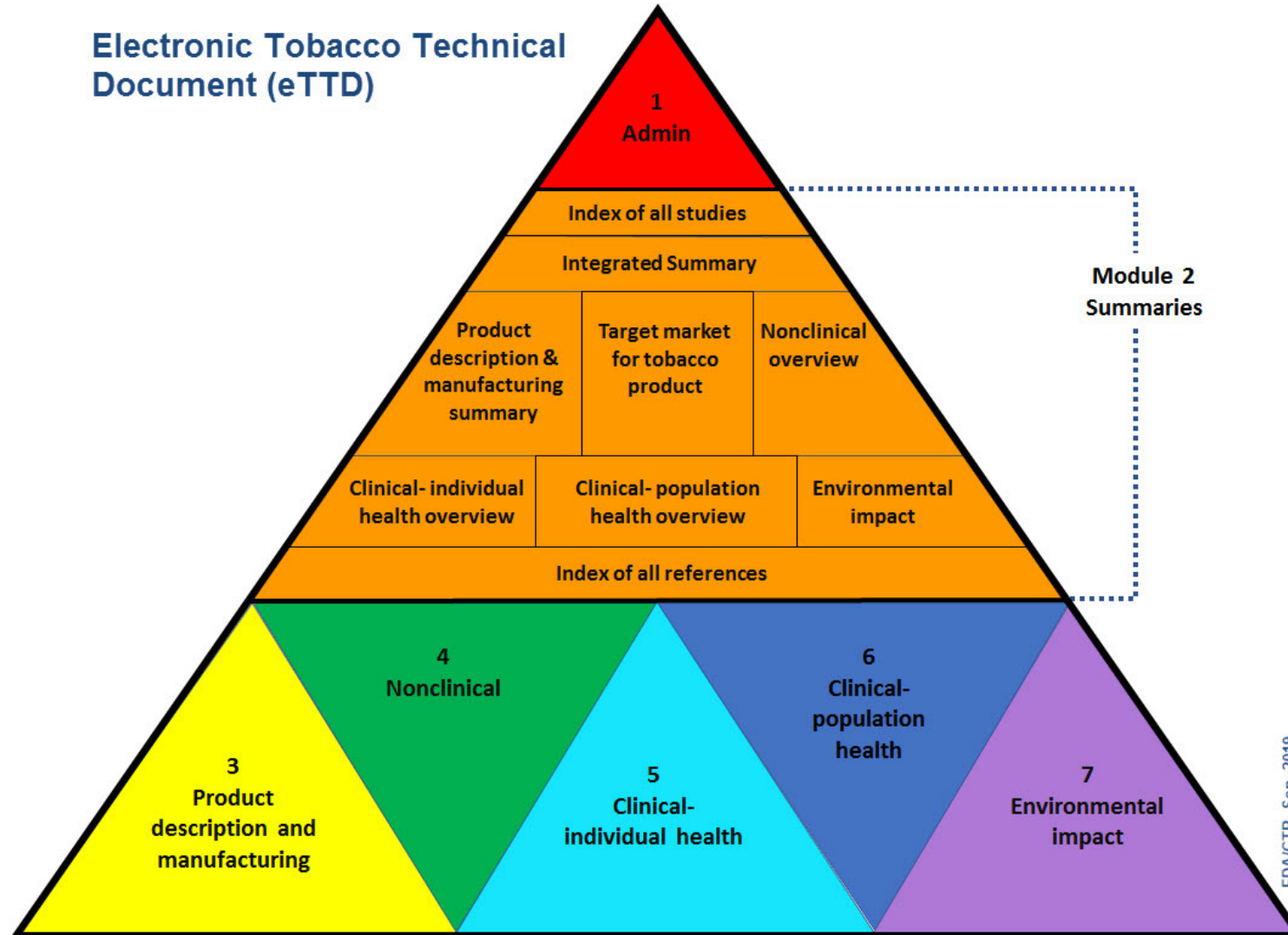


Structured



ORGANIZATION OF A SUBMISSION

Electronic Tobacco Technical Document (eTTD)



FDA/CTP, Sep. 2019

CURRENT ESUBMISSION CHALLENGES

Issues	Impact
Non-uniform submissions	
Manual and duplicate data entry	
Manual loading and viewing of submissions	
Difficulty finding information	
Difficulty referencing shared product documents and content	

BENEFITS OF STRUCTURED SUBMISSIONS

Benefits

Predictable, repeatable document naming and organization

Automated flow of data and documents

Automated capture and reuse of submission information

Support for grouped submissions

Cross-referencing of previously submitted content

Impact



SUBMISSION TABLE OF CONTENTS



Modules, *First Level*

eTTD Modules

Administrative

2. Summaries

3. Product Description and Manufacturing

4. Nonclinical

5. Clinical- Product Impact on Individual Health

6. Clinical- Product Impact on Population Health

7. Environmental Impact

*See [Electronic Submission File Formats and Specifications](#)

SUBMISSION TABLE OF CONTENTS



MODULE 1, *Second Level*

MODULE 1, ADMINISTRATIVE

- | |
|---|
| 1.1 submission form |
| 1.2 cover letter |
| 1.3 administrative information |
| 1.4 industry to FDA correspondence regarding application status |
| 1.5 industry to FDA correspondence-other |
| 1.6 meetings with Industry |
| 1.7 dispute resolution |
| 1.8 industry periodic report |
| 1.9 product labels and labeling |
| 1.10 product promotional material |
| 1.11 grandfather evidence |
| 1.12 FDA to industry correspondence |
| 1.13 masterfile authorization |
| 1.14 health documents [904(a)(4)] |
| 1.15 requested documents [904(b)] |

*See [Electronic Submission File Formats and Specifications](#)

SUBMISSION TABLE OF CONTENTS



MODULE 2, *Second Level*

MODULE 2, SUMMARY

- 2.1 index of all studies
- 2.2 integrated summary
- 2.3 product description and manufacturing summary
- 2.4 target market for tobacco product
- 2.5 nonclinical overview
- 2.6 clinical- individual health overview
- 2.7 clinical- population health overview
- 2.8 environmental impact summary
- 2.9 index of all referenced literature

*See [Electronic Submission File Formats and Specifications](#)

SUBMISSION TABLE OF CONTENTS



MODULE 3, *Second Level*

MODULE 3, PRODUCT DESCRIPTION AND MANUFACTURING

- 3.1 product design and specification
- 3.2 ingredients, additives, and constituents
- 3.3 product performance
- 3.4 tobacco product comparisons
- 3.5 tobacco product manufacture
- 3.6 other tobacco product features
- 3.7 referenced literature

*See [Electronic Submission File Formats and Specifications](#)

SUBMISSION TABLE OF CONTENTS



MODULE 4, *Second Level*

MODULE 4, NONCLINICAL

- 4.1 tabular listing of all nonclinical studies
- 4.2 nonclinical studies
- 4.3 nonclinical behavioral studies
- 4.4 nonclinical abuse liability studies
- 4.5 nonclinical study model or analysis
- 4.6 nonclinical literature review
- 4.7 other documents relating to research [911(d)(5)] or 910(b)(1)]
- 4.8 referenced literature

*See [Electronic Submission File Formats and Specifications](#)

SUBMISSION TABLE OF CONTENTS



MODULE 5, *Second Level*

MODULE 5, CLINICAL- PRODUCT IMPACT ON INDIVIDUAL HEALTH

- 5.1 tabular listing of individual health studies
- 5.2 abuse liability study (human) – PK and PD or subjective effects
- 5.3 actual use study - use behaviors or health outcomes
- 5.4 other clinical study reports and related information
- 5.5 adverse experience reports
- 5.6 individual health literature review
- 5.7 other documents relating to research [911(d)(5)] or 910(b)(1)]
- 5.8 referenced literature

*See [Electronic Submission File Formats and Specifications](#)

SUBMISSION TABLE OF CONTENTS



MODULE 6, *Second Level*

MODULE 6, CLINICAL – PRODUCT IMPACT ON POPULATION HEALTH

- 6.1 tabular listing of all population health studies
- 6.2 tobacco product perception and intention study
- 6.3 behavioral epidemiology (observational) study
- 6.4 biomarker epidemiology (observational) study
- 6.5 health risk epidemiology (observational) study
- 6.6 population modeling and analysis
- 6.7 postmarket surveillance and postmarket study plan or protocol
- 6.8 population health literature review
- 6.9 other documents relating to research [911(d)(5)] or 910(b)(1)]
- 6.10 referenced literature

*See [Electronic Submission File Formats and Specifications](#)

SUBMISSION TABLE OF CONTENTS



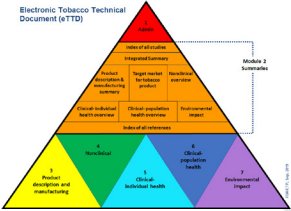
MODULE 7, *Second Level*

MODULE 7, ENVIRONMENTAL IMPACT

- 7.1 need for the proposed actions
- 7.2 potential environmental impacts of the proposed actions
and alternatives - manufacturing the new products
- 7.3 potential environmental impacts of the proposed actions
and alternatives – use of the new products
- 7.4 potential environmental Impacts of the proposed actions
and alternatives – disposal of the new products
- 7.5 mitigation of environmental effects
- 7.6 alternatives to the proposed actions
- 7.7 list of preparers
- 7.8 listing of agencies and persons consulted
- 7.9 other documents relating to research [911(d)(5)] or 910(b)(1)]
- 7.10 referenced literature
- 7.11 EA appendices
- 7.12 EA confidential appendices

*See [Electronic Submission File Formats and Specifications](#)

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- CTP Portal

“...FDA IS PROPOSING THAT THE PMTA AND ALL SUPPORTING DOCUMENTS MUST BE SUBMITTED TO FDA IN AN ELECTRONIC FORMAT THAT THE AGENCY CAN PROCESS, REVIEW, AND ARCHIVE...”



Usability in FDA’s Review Environment

- PDF files directly from source file
- Table of Contents
- Working hypertext links and bookmarks
- Legible, English language content
- Electronically readable, valid FDA form

“...FDA IS PROPOSING THAT THE PMTA AND ALL SUPPORTING DOCUMENTS MUST BE SUBMITTED TO FDA IN AN ELECTRONIC FORMAT THAT THE AGENCY CAN PROCESS, REVIEW, AND ARCHIVE...”

Integrity and Security

- Don't submit damaged media
- Test submission by installing onto another location and opening
- Virus scan all files
- Avoid security settings in files, e.g., encryption, password protection, printing restrictions
- Avoid altering eSubmission package files outside of eSubmitter after they've been packaged and signed

“...FDA IS PROPOSING THAT THE PMTA AND ALL SUPPORTING DOCUMENTS MUST BE SUBMITTED TO FDA IN AN ELECTRONIC FORMAT THAT THE AGENCY CAN PROCESS, REVIEW, AND ARCHIVE...”



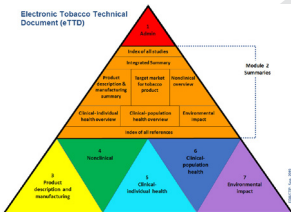
Acceptable File Formats

- ✓ **PDF, DOCX, TXT, XPT, CSV, XLS, XLSX, XML, JPG, GIF...**
- ✓ Filename extension identifies the file type

Filenaming

- ✓ Avoid special characters or foreign characters, e.g., #, %, ., &, ><
- ✓ Avoid deep subfolders
- ✓ Keep path and filename < 180 length
- ✓ Use SaS transport file (.xpt) for analysis datasets

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FDA SUBMISSION TOOLS AND SYSTEMS



Safety Reporting Portal

The Safety Reporting Portal (SRP) streamlines the process of reporting product safety issues to the Food & Drug Administration (FDA) and the National Institutes of Health (NIH).

Whatever your role, (manufacturer, health care professional, researcher, public health official, or concerned citizen), when you submit a safety report through this medicine, and other products that touch us all.

Parts of this website have been translated from English to Spanish. Pages that have this link to see the page in Spanish (Español). Click "In English" to see the page in considered official. Currently, report questions are only in English and reports should only be submitted in English. Thank you for using the FDA Safety Reporting Portal.

Who Should Submit a Safety Report?

Organizations and people in certain professional roles, such as the following, may be required by law to submit safety reports under some circumstances:

- Food Manufacturers, Processors, Packers, and Holders
- Researchers
- An applicant of an approved drug product or a manufacturer, distributor or packer listed on the label of any marketed drug product
- Drug Manufacturers
- Sponsors, sponsor-investigators of investigational drugs and biologics
- Dietary supplement manufacturers, packers, and distributors

Others, including healthcare providers, public health officials, and other professionals, as well as consumers and concerned citizens, may voluntarily submit reports if they encounter safety issues with a product and/or unanticipated harmful effects that they believe are related to the product.

Learn more about mandatory and voluntary reporting.

Begin Reporting Here

1. Login

EMAIL:

PASSWORD:

Remember me

2. Report As Guest

Not ready to create an account but would like to submit a report?

You can do that here.

Account Benefits

- Save a draft
- Easier follow up
- View submissions
- Faster data entry

What is the CTP Portal?

The U.S. Food and Drug Administration's (FDA) Center for Tobacco Products (CTP) developed the CTP Portal as part of its initiative to improve submission processing and to foster interaction with industry. The CTP Portal allows industry to use the embedded upload feature to transmit eSubmitter-generated submissions; the new transmission method offers industry an alternative to the agency's existing WebTrader Hosted Solution.

The CTP Portal is intended for use by regulated tobacco industry, including manufacturers, importers, and distributors who make submissions to CTP. The CTP Portal should improve transparency and facilitate communication to speed issue resolution that may otherwise hinder processing and/or access to industry submissions.

How to Get Access

Each regulated tobacco organization should have one or more Industry Account Managers (IAMs) who assume responsibility for managing users of the CTP Portal for their respective organization. These Industry Account Managers are able to add new users, grant corresponding user roles and permissions, lock and unlock user accounts, and see information for existing user accounts.

If your organization has an IAM: If other members in your organization currently have user accounts, we encourage you to reach out to your organization's Industry Account Manager and request that they create a new user account on your behalf. They will be able to designate the appropriate user role for your account, including within an Industry Account Manager (IAM) account. CTP staff will review your request and communicate CTP Portal User account updates as they become available.

If your organization does not have an IAM: If you are not aware of any members of your organization currently having CTP Portal user accounts, please [contact us](#) to designate an IAM. IAMs are able to add new users, grant corresponding user roles and permissions, lock and unlock user accounts, and see information for existing user accounts.

Supported Browsers

For optimal performance, we recommend using Internet Explorer (IE) 11, or the latest versions of Mozilla Firefox or Google Chrome. If using Internet Explorer (IE) 10, or earlier versions of Firefox and Chrome, you may experience minor visual deviations and limitations. Please note other browsers such as Safari 5 and below, IE 9 and below, as well as Linux/Unix specific browsers (e.g., Konqueror, Camino) are not supported.

Computer Security

Before using FDA Industry Systems (FIS), FDA strongly encourages all users to have current antivirus and anti-spyware software installed on your computer to help ensure the privacy of information being entered.

U.S. Food and Drug Administration

FDA Electronic Submissions Gateway

User ID:

Password:

I agree to the terms set forth in the System Notification below.

Remember me on this computer

Module 2 Summaries

1 Admin

2 Product description and manufacturing

3 Nonclinical

4 Clinical - individual health overview

5 Clinical - population health overview

6 Environmental impact

7 Index of all references

8 Index of all studies

9 Target market for tobacco product

10 Nonclinical overview

11 Environmental impact

12 Product description & manufacturing summary

13 Clinical - individual health overview

14 Clinical - population health overview

15 Index of all references

16 Index of all studies

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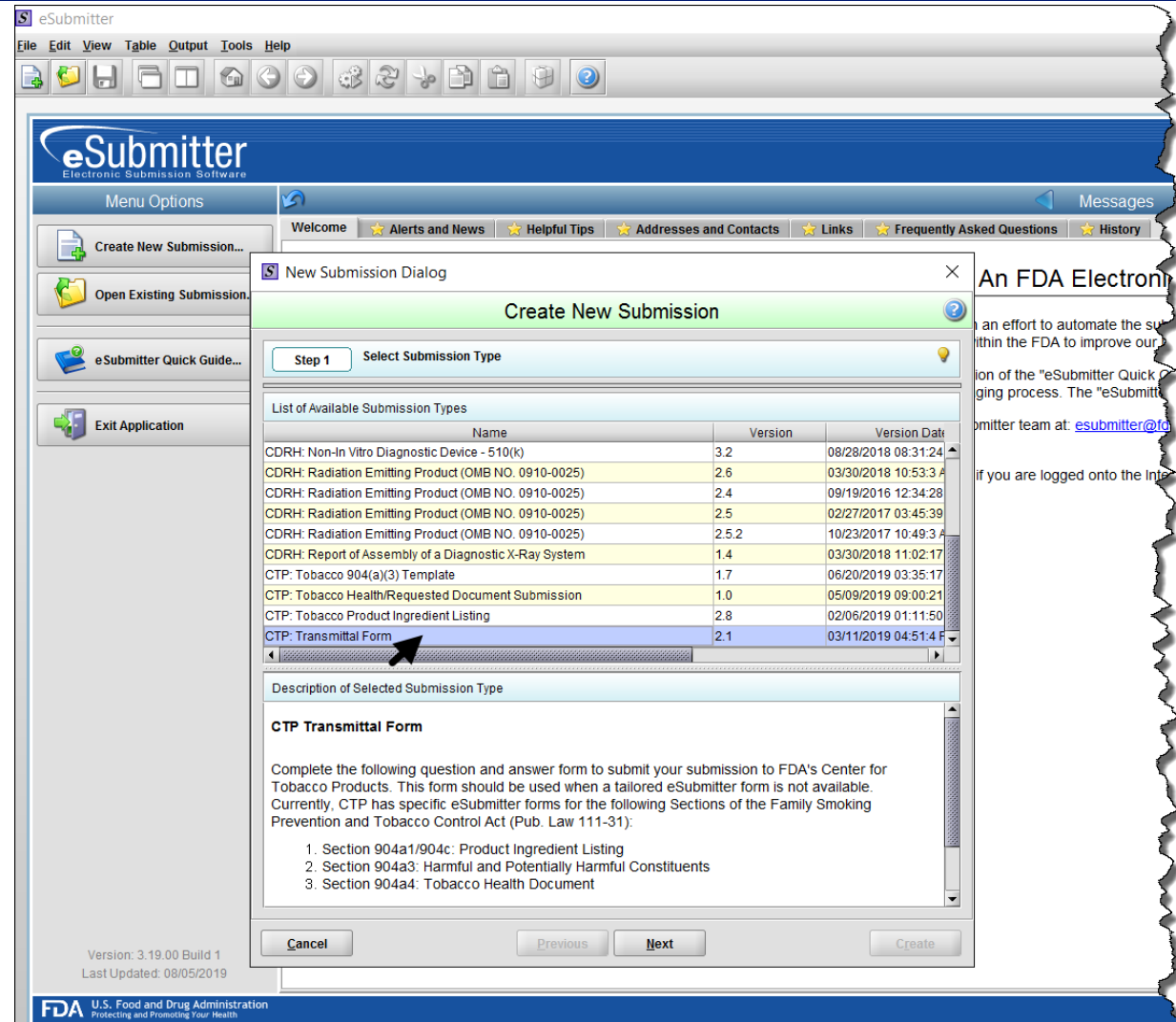
<https://www.fda.gov/industry/fda-esubmitter>

Then click on the Download & Installation link

USING eSUBMITTER

1. Open eSubmitter
2. Create New Submission
3. Select a CTP Template

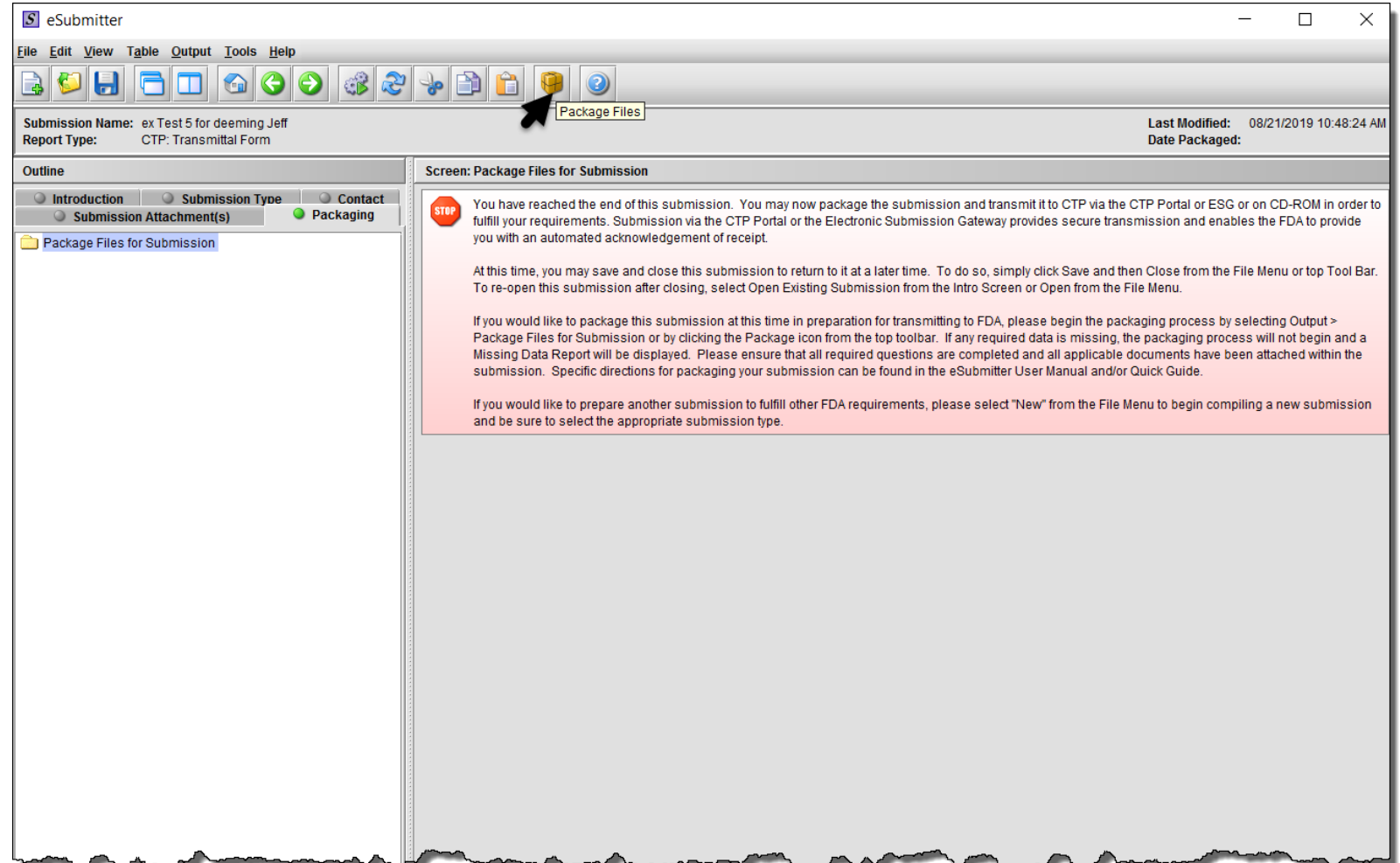
The Template will then walk you through entering more



USING eSUBMITTER

At the end, you will package the submission

Create a zip file that you can then upload to Portal



eSubmitter User Guide.

- Contact CTP
 - For eSubmitter technical support, email esubmitter@fda.hhs.gov or call 1-877-CTP-1373
- See CTP's eSubmitter Submission Checklist and Technical Working Instructions for help preparing your electronic submission. Persons with disabilities having problems accessing the PDF may call 1-877-CTP-1373 for assistance.
- Watch video tutorials using eSubmitter

CTP PORTAL LOGIN

- Upload eSubmitter submission files
- Ability to view submission administrative information
- Link to CTP Portal: <https://ctpportal.fda.gov/ctpportal/login.jsp>

- Account management performed by an Industry Account Manager (IAM)
- Link to IAM Request info: <https://www.fda.gov/tobacco-products/manufacturing/request-industry-account-manager-iam-ctp-portal>



CTP PORTAL



Welcome screen

CTP Portal Smith, Jeffrey | ABC Launch U

[Home](#) [Messages 63](#) [Submissions](#)

Welcome to the CTP Portal

The U.S. Food and Drug Administration's (FDA), Center for Tobacco Products (CTP) developed the CTP Portal as part of its initiative to improve submission process and facilitate interaction with industry stakeholders. The CTP Portal allows industry stakeholders to use the embedded upload feature to transmit eSubmitter-generated submissions; this new transmission method offers industry stakeholders an alternative to the Agency's existing WebTrader Hosted Solution.

The CTP Portal is intended for use by stakeholders in the regulated tobacco industry, including manufacturers, importers, and distributors who make submissions. The CTP Portal should improve transparency and facilitate communication to speed issue resolution that may otherwise hinder processing and/or access to industry submissions.

The CTP Portal does not replace existing FDA systems and corresponding requirements, including but not limited to Tobacco Registration and Product Listing submissions made via the FDA Unified Registration Listing Systems (FURLS).

[Let's Get Started](#)

Recent Regulatory Files

Date Issued	File Type	STN
08/16/2019	Acknowledgement Letter	GF1904143
08/15/2019	Acknowledgement Letter	HD0000966
08/15/2019	Acknowledgement Letter	GF1904142
08/02/2019	Acknowledgement Letter	RP1915366
08/02/2019	Acknowledgement Letter	RP1915365

Displaying 5 most recent [View All](#)

Recent Notifications

- 08/24/2019 05:22 AM [RD](#)
A submission is now available for viewing in the CTP Portal
- 08/16/2019 04:35 PM [GF](#)
A submission is now available for viewing in the CTP Portal
- 08/16/2019 12:08 PM
The CTP Portal User Admin has changed
- 08/15/2019 06:35 PM [HD](#)
A submission is now available for viewing in the CTP Portal

Displaying 4 most recent

Recent Uploads

File Name	User's Name	Status Date	File Count	Status
GF0828.zip	Niederriter, Kayla	08/29/2019	3	Submission in Progress
TI0828.zip	Niederriter, Kayla	08/29/2019	3	Submission in Progress
LoaderTestHD-SmithJ.zip	Smith, Jeffrey	08/26/2019	10	Submission Received
LoaderTestRD-SmithJ.zip	Smith, Jeffrey	08/26/2019	10	Submission Received

Displaying 4 most recent

Upload tool

1 UPLOAD HISTORY 2 UPLOAD FILE 3 CONFIRMATION

CTP Portal Upload Tool

allows you to upload and transmit submission packages generated using FDA's eSubmitter. For additional details regarding the Upload Tool as well as instructions for downloading the FDA eSubmitter, refer to the Upload Tool section of the CTP Portal Help module.

[Upload eSubmitter File](#)

VIEW HISTORY View Only My Uploads

User's Name	Upload Status Date	Package Description	Package ID	Status	
Doe, Jane	07/01/2016	Upload History Check	I-E-000-00-0EC-CA	Upload Successful	
T_Man	Brown, Towanda	06/29/2016	Upload TC Amendment	I-E-000-00-0EC-C6	Upload Successful
annual_P	Brown, Towanda	06/29/2016	Uploaded TC	I-E-000-00-0EC-C5	Upload Successful
40+MB.	Henry, Amy	04/21/2016	Resuming this upload this is a test of the upload large files	I-E-000-00-0EB-B2	Upload Successful
SubPkg	Brown, Towanda	03/24/2016	Test description	I-E-000-00-0C1-B8	Upload Successful
SubPkg	Brown, Towanda	03/24/2016	Test upload package description	I-E-000-00-0C1-B7	Upload Successful
Submis	Henry, Amy	03/15/2016	test file	I-E-000-00-0C1-AB	Upload Successful

Display 1-7 of 7 items

CTP PORTAL INDUSTRY ACCOUNT MANAGER (IAM)



An IAM request requires two completed and signed forms

- IAM Cover Letter signed by an authorized representative, *e.g. CEO or other executive*
- Rules of Behavior signed by the designated IAM

With a completed, signed IAM Cover Letter and Rules of Behavior, an IAM request can usually be fulfilled within 7-14 business days; *Don't wait until a deadline is near*

The IAM receives an email to complete the account setup

- The email link is valid for 24 hours,
- CTP creates the first IAM then IAM can create additional Portal accounts for their company

CTP Portal account passwords need to be reset every 90 days by each Portal user

For assistance contact CTPeSub@fda.hhs.gov or call 1-877-287-1373

<https://www.fda.gov/tobacco-products/manufacturing/request-industry-account-manager-iam-ctp-portal>

Helpful Tips:

- ✓ IAM form must be signed by an authorized representative who is a direct employee of the organization
- ✓ Complete all fields legibly
- ✓ Include full legal name of organization
 - ✓ Do not write “self-employed”
- ✓ Include full legal address of organization
 - ✓ Do not include personal addresses
- ✓ Include correct email address
- ✓ Ensure all required signatures are included on both forms
 - ✓ Authorized Representative should sign the IAM Request Form
 - ✓ Designated IAM should sign the Rules of Behavior (ROB)
- ✓ Use Adobe digital signatures with date stamp or wet ink

Technical questions related to CTP Portal, and electronic submissions to CTP:

Call 1.877.CTP.1373 (1.877.287.1373) Monday-Friday, 9 a.m. – 4 p.m. EDT.

Select option 2

Email CTPeSub@fda.hhs.gov

- [CTP Glossary \(https://www.fda.gov/node/370828\)](https://www.fda.gov/node/370828)
- [Product Category and SubCategory \(https://www.fda.gov/media/124658/download\)](https://www.fda.gov/media/124658/download)
- Product Grouping Spreadsheet
- [Resources for Electronic Submissions \(https://www.fda.gov/tobacco-products/compliance-enforcement-training/manufacturing\)](https://www.fda.gov/tobacco-products/compliance-enforcement-training/manufacturing)
 - [Electronic Submission File Formats and Specifications \(https://www.fda.gov/media/122970/download\)](https://www.fda.gov/media/122970/download)
 - [Overview of the Electronic Submissions Process for Industry \(https://www.fda.gov/media/111668/download\)](https://www.fda.gov/media/111668/download)
 - [Common Errors that Delay Submission Processing \(https://www.fda.gov/media/111686/download\)](https://www.fda.gov/media/111686/download)
- [Using eSubmitter to Prepare Tobacco Product Submissions https://www.fda.gov/industry/fda-esubmitter/using-esubmitter-prepare-tobacco-product-submissions\)](https://www.fda.gov/industry/fda-esubmitter/using-esubmitter-prepare-tobacco-product-submissions)
- [CTP Portal https://ctpportal.fda.gov/ctpportal/login.jsp\)](https://ctpportal.fda.gov/ctpportal/login.jsp)



Website:

Audience can respond at: PolleEv.com/crystalallar597

Text messaging:

Text [CRYSTALALLAR597](https://www.cdc.gov/crystalallar597) to [22333](https://www.cdc.gov/22333) to join the session

