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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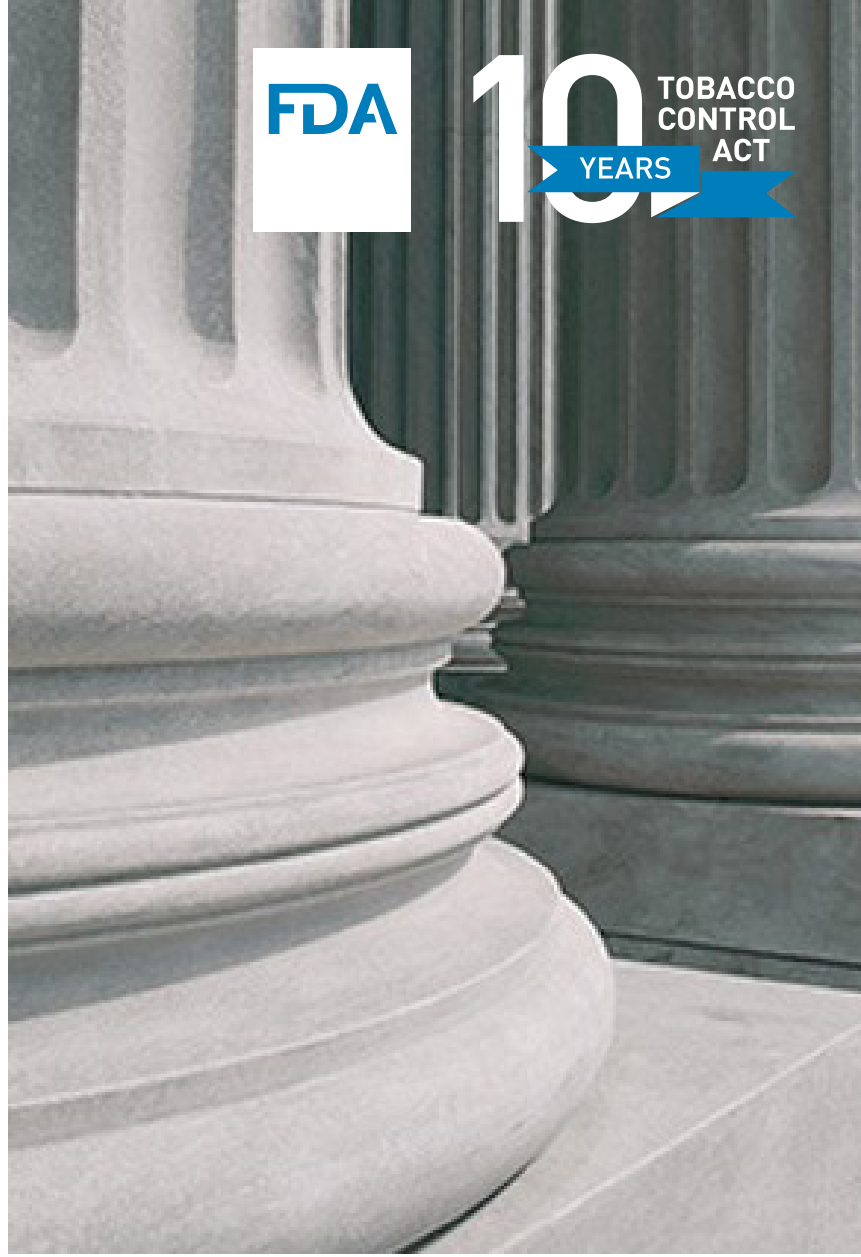


POLLEVERYWHERE – THERE WILL BE A QUIZ

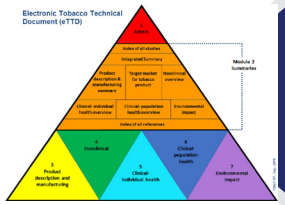
Website:
Audience can respond at: PollEv.com/crystalallar597

Text messaging:
Text CRYSTALALLAR597 to 22333 to join the session

AGENDA

- 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

GROUPING

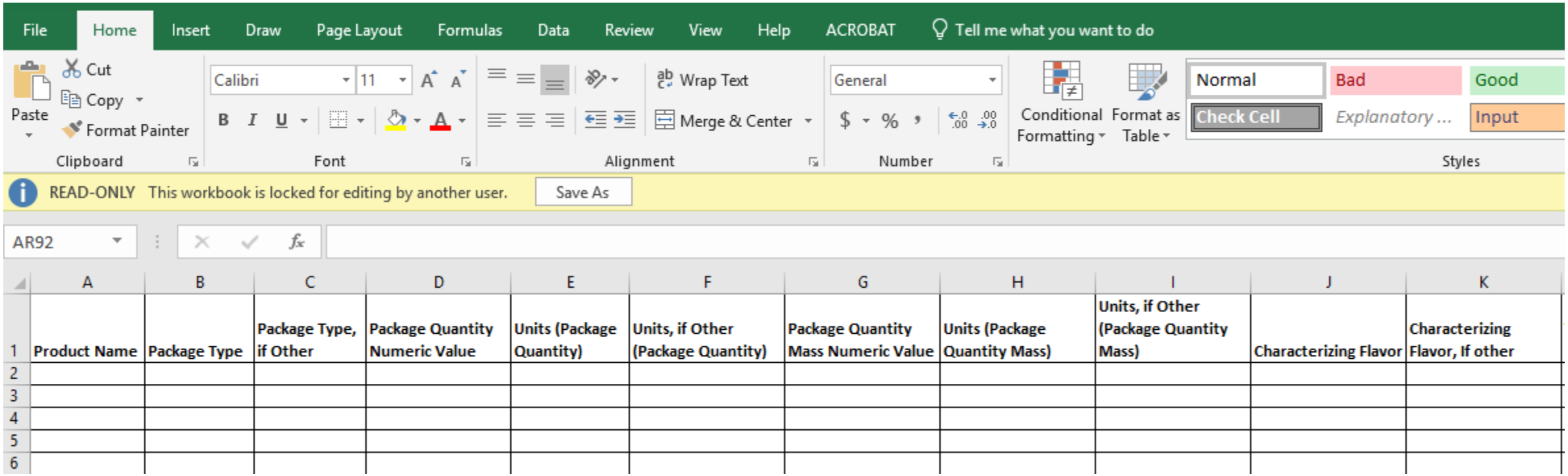
Background

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

Multiple Products, One Submission to CTP

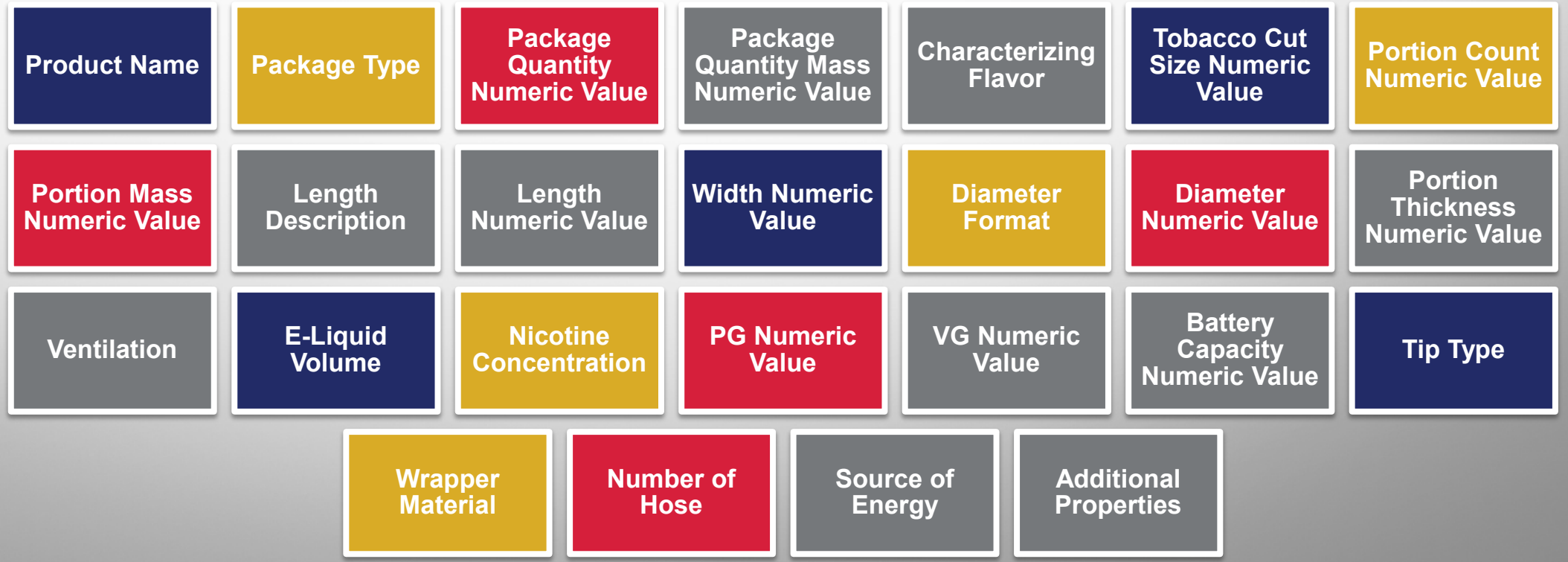
- If same:
  - Domestic Manufacturer or Importer
  - Submission type (PMTA, SE, etc.)
  - Product category
  - Product subcategory

GROUPING

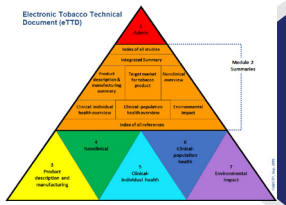


	A	B	C	D	E	F	G	H	I	J	K
1	Product Name	Package Type	Package Type, if Other	Package Quantity Numeric Value	Units (Package Quantity)	Units, if Other (Package Quantity)	Package Quantity Mass Numeric Value	Units (Package Quantity Mass)	Units, if Other (Package Quantity Mass)	Characterizing Flavor	Characterizing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

GROUPING


Product Name
Package Type
Package Quantity Numeric Value
Package Quantity Mass Numeric Value
Characterizing Flavor
Tobacco Cut Size Numeric Value
Portion Count Numeric Value
Portion Mass Numeric Value
Length Description
Length Numeric Value
Width Numeric Value
Diameter Format
Diameter Numeric Value
Portion Thickness Numeric Value
Ventilation
E-Liquid Volume
Nicotine Concentration
PG Numeric Value
VG Numeric Value
Battery Capacity Numeric Value
Tip Type
Wrapper Material
Number of Hose
Source of Energy
Additional Properties

Organization



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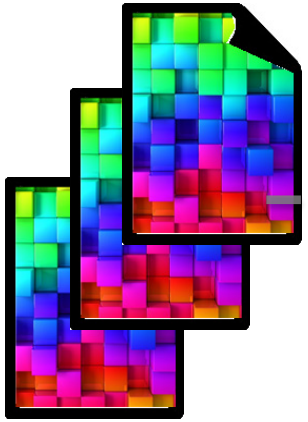
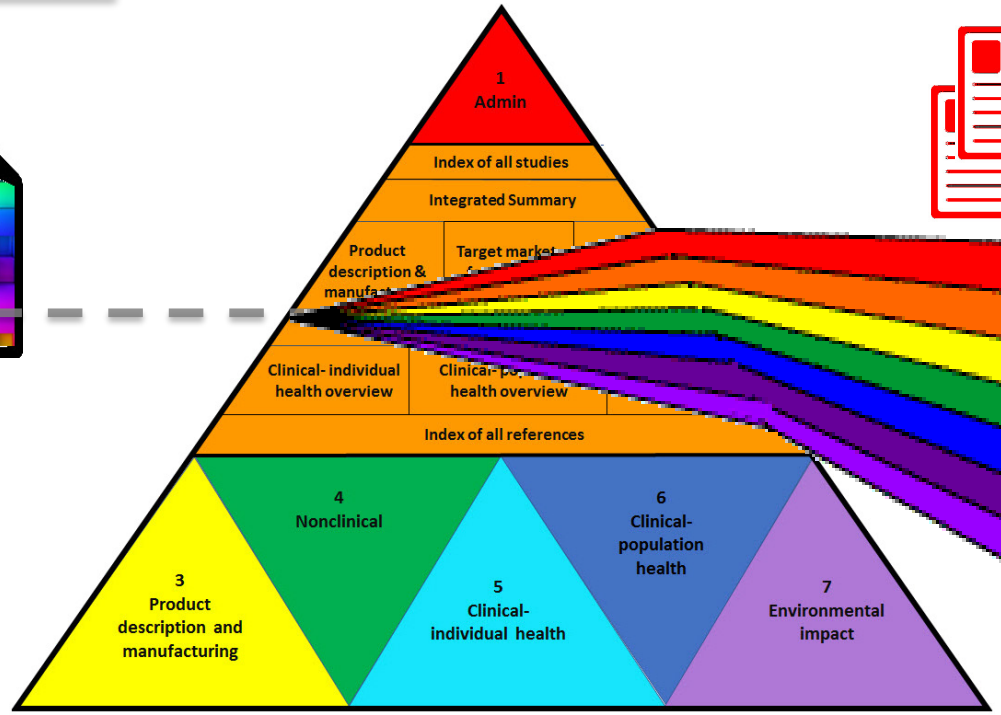
TOBACCO TECHNICAL DOCUMENT

FDA

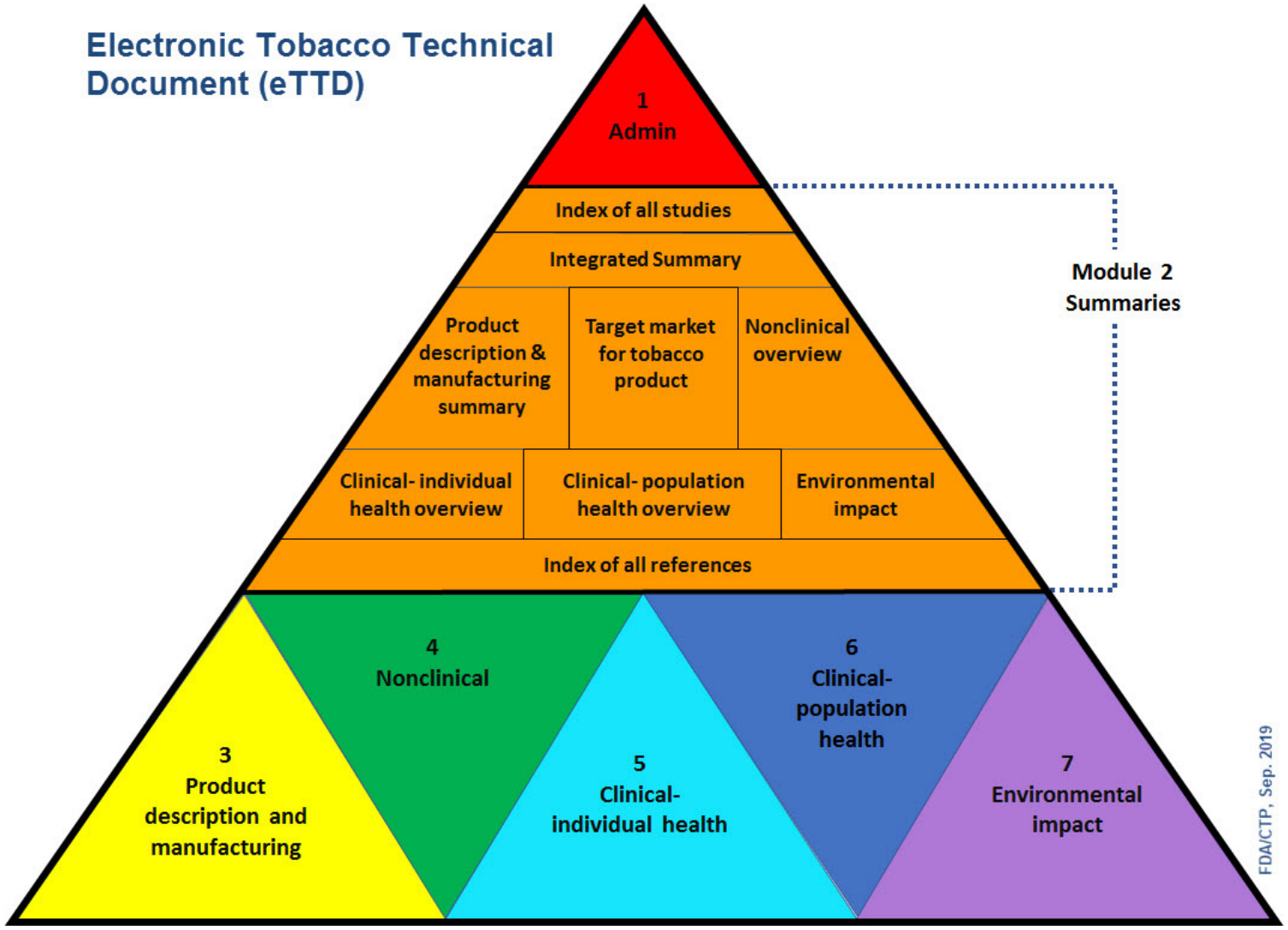
UnStructured





Structured

ORGANIZATION OF A SUBMISSION



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	Impact
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	

SUBMISSION TABLE OF CONTENTS

FDA

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

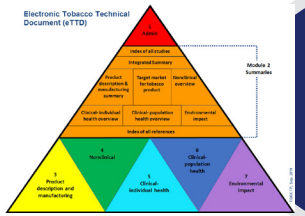
SUBMISSION TABLE OF CONTENTS

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

Organization



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"…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…"

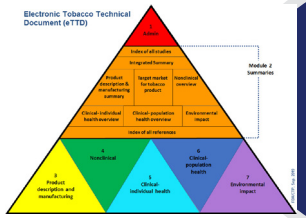
Acceptable File Formats

- ✓ **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

Organization



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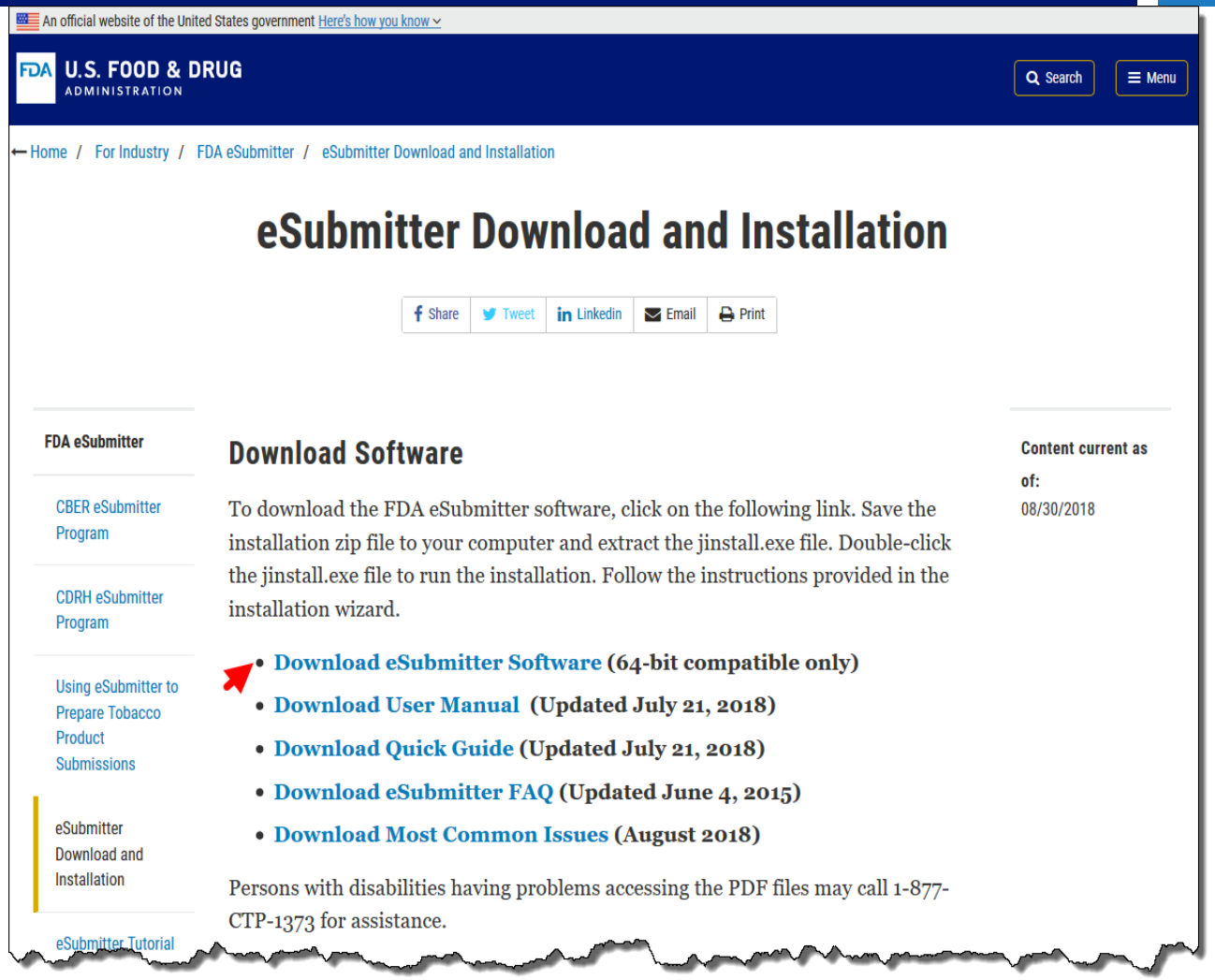
FDA SUBMISSION TOOLS AND SYSTEMS

FDA eSUBMITTER

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

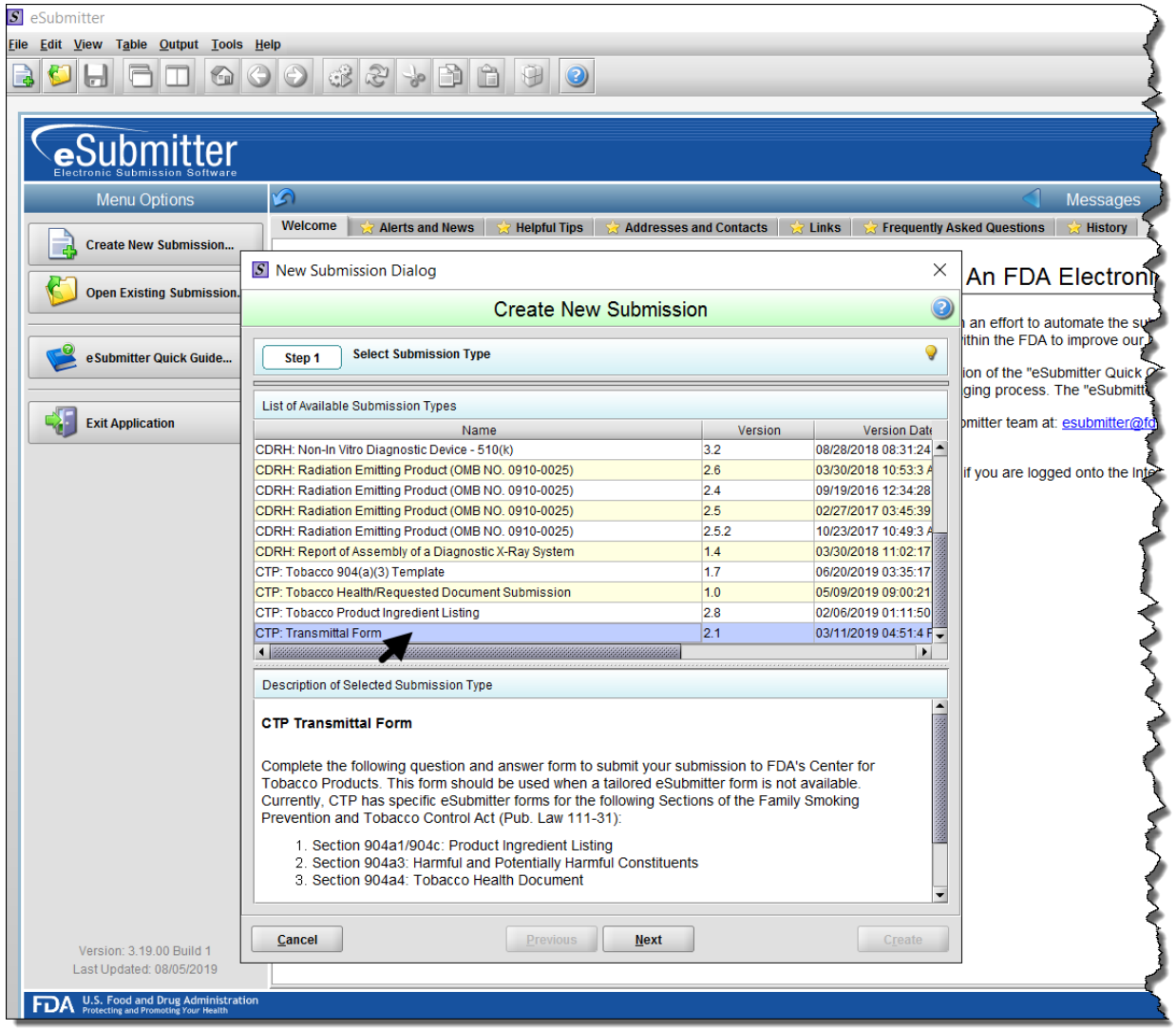
Then click on the Download & Installation link



USING eSUBMITTER

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

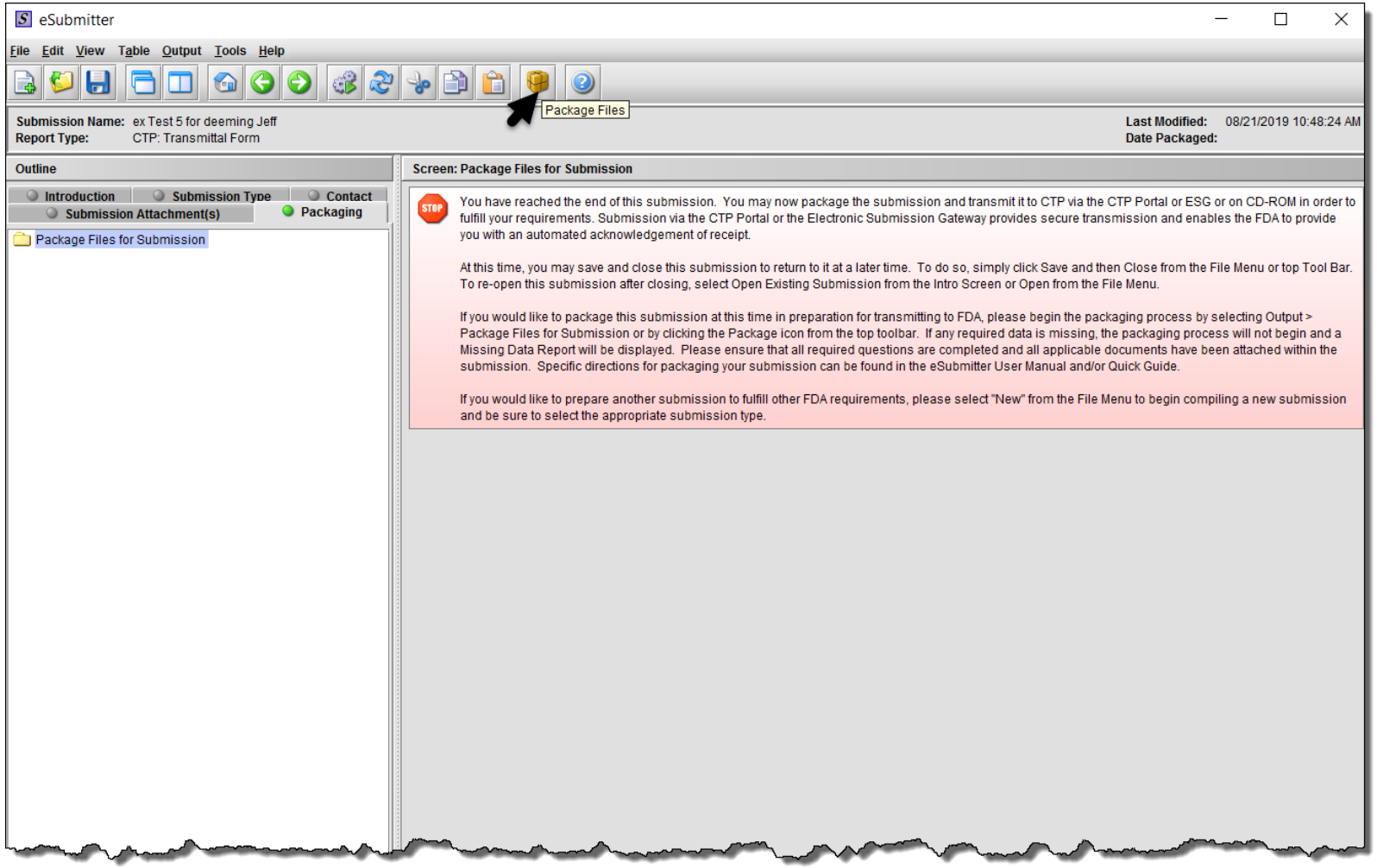
The Template will then walk you through entering more



USING eSUBMITTER

At the end, you will package the submission

Create a zip file that you can then upload to Portal

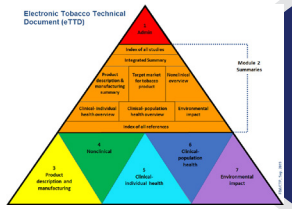


eSUBMITTER RESOURCES

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

Organization



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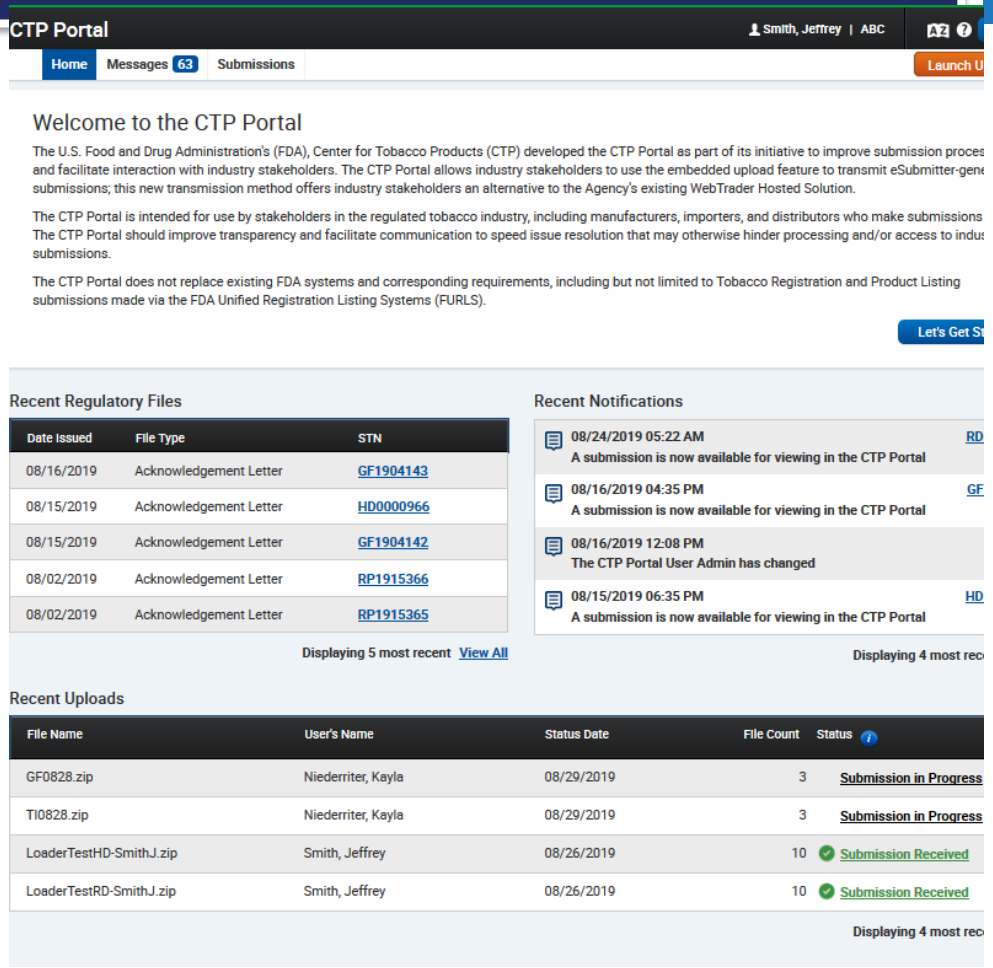
CTP PORTAL LOGIN

- 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

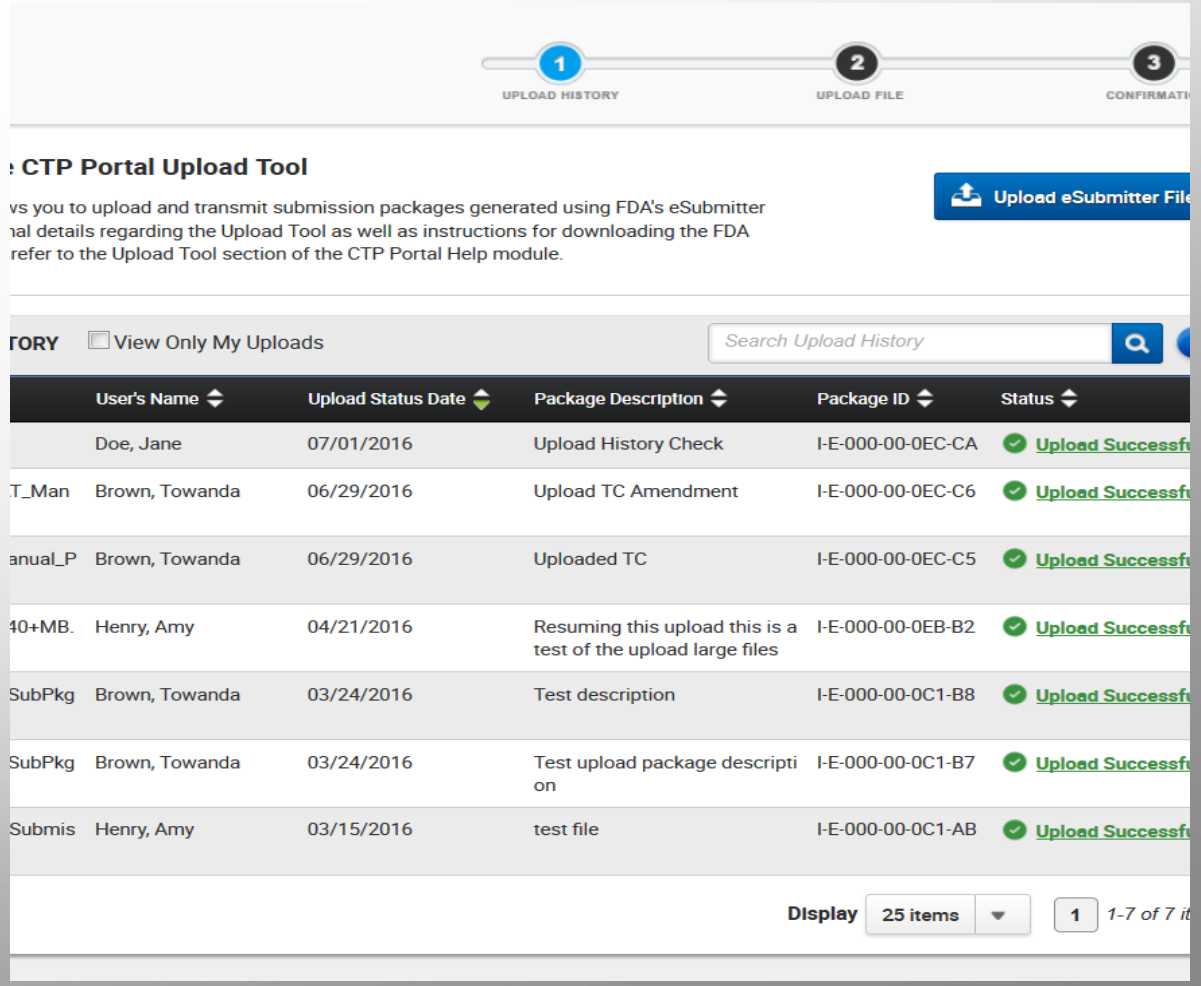
CTP PORTAL

Welcome screen



CTP PORTAL

Upload tool



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

CTP PORTAL INDUSTRY ACCOUNT MANAGER (IAM)

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

CTP eSUBMISSION HELPDESK

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

RESOURCES

- CTP Glossary (https://www.fda.gov/node/370828)
- Product Category and SubCategory (https://www.fda.gov/media/124658/download)
- Product Grouping Spreadsheet
- Resources for Electronic Submissions (https://www.fda.gov/tobacco-products/compliance-enforcement-training/manufacturing)
  - Electronic Submission File Formats and Specifications (https://www.fda.gov/media/122970/download)
  - Overview of the Electronic Submissions Process for Industry (https://www.fda.gov/media/111668/download)
  - Common Errors that Delay Submission Processing (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)
- *CTP Portal* https://ctpportal.fda.gov/ctpportal/login.jsp)

POLLEVERYWHERE

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