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Deeming Rule Compliance Requirements

Webinar

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Presenters

- **Azim Chowdhury** joined K&H in 2010 and practices in the area of FDA law with a focus on food, tobacco and e-vapor products. Mr. Chowdhury advises e-vapor manufacturers, distributors retailers and trade associations on matters of state, FDA and international regulatory compliance.

- **Ben Wolf** joined K&H in 2016 and also practices FDA law, with a focus on of food, tobacco and e-vapor products. Prior to joining K&H, Mr. Wolf worked for the FDA as a regulatory counsel in the Center for Tobacco Products (CTP) and Office of Regulatory Affairs (ORA).

Agenda

- Deeming Rule Background
- New Compliance Deadlines
- Overview of Compliance Requirements and Demonstration
  - Registration and Product Listing
  - Health Document Notification
  - Ingredient Listing
- Purchase our E-Vapor Law Symposium replay:

  https://www.fdalaws.us/symposium2017

Deeming Rule - Background

- Published May 10, 2016
- Effective August 8, 2016
  - All “tobacco products” now subject to FDA authority and Tobacco Control Act
  - “Compliancy Policy” deadlines established for various TCA requirements
  - No new products can enter market after effective date without FDA authorization
  - Requirements for retailers, warnings, adulteration, misbranding and avoiding modified risk claims, etc.

What's not there

- No GMP, ISO or "clean room" requirements
- No ingredient or flavor prohibitions
- No maximum nicotine concentrations
- No online sales restriction
- No device restrictions or battery standards
- No ban or limit on advertising, sponsorship, branded items, product naming

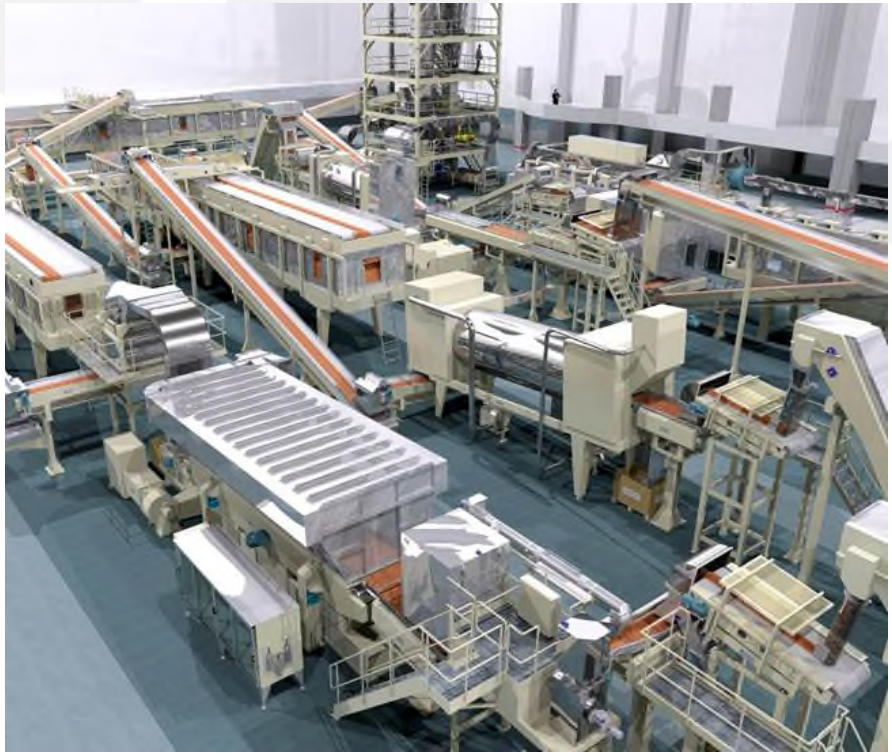
None of the above ….yet

More to come…

The Deeming Regulation is a "foundational" rule – additional requirements will come from FDA in the future

Compliance Requirements for Manufacturers

Are you a tobacco product manufacturer?



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Who is a Manufacturer?

- Any person, including any repacker or relabeler, who (A) manufactures, fabricates, assembles, processes, or labels a tobacco product; or (B) imports a finished tobacco product for sale or distribution in the United States

Who is a Manufacturer?

- Vape shops that create or modify products are considered tobacco product manufacturers
- New draft guidance clarifies permitted vape shop activities:
  - *Interpretation of and Compliance Policy for Certain Label Requirement; Applicability of Certain Federal Food, Drug, and Cosmetic Act Requirements to Vape Shops: http://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/ucm536995.htm*

Small-Scale Tobacco Manufacturers

- Must employ 150 or fewer FTEs and have annual total revenues ≤ $5M
- FDA will consider revenues from the company as a whole, including the parent and all subsidiaries under the same control

Previous Compliance Deadlines

Prior to May 1, 2017

Requirement	Deadline for Large-Scale Manufacturers	Deadline for Small-Scale Manufacturers
Registration of U.S. manufacturing establishments and submission of List of Products manufactured in such establishments	June 30, 2017 (originally December 31, 2016)	June 30, 2017 (originally December 31, 2016)
Submission of Health Document Notification	February 8, 2017	August 8, 2017 (originally February 8, 2017)
Submission of Ingredients Listing Reports	August 8, 2017 (originally February 8, 2017)	February 8, 2018 (originally August 8, 2017)
Premarket Tobacco Product Application (PMTA) for products on market on August 8, 2016	August 8, 2018	August 8, 2018
Submission of Harmful and Potentially Harmful Constituents (HPHCs) Reports	August 8, 2019	August 8, 2019

New Dates Announced

- May 1, 2017 e-mail from FDA's Stakeholder Relations Office stated that FDA is delaying enforcement of all future compliance deadlines set for May 10, 2017 or later
- Purpose is to allow new leadership more time to consider issues raised by Deeming that are now the subject of multiple lawsuits in federal court
- New Guidance forthcoming

New Compliance Deadlines

Pending Revised/Update FDA Guidance

Requirement	Deadline for Large-Scale Manufacturers	Deadline for Small-Scale Manufacturers
Registration of U.S. manufacturing establishments and submission of List of Products manufactured in such establishments	September 30, 2017	September 30, 2017
Submission of Health Document Notification	February 8, 2017	November 8, 2017
Submission of Ingredients Listing Reports	November 8, 2017	May 8, 2018
Premarket Tobacco Product Application (PMTA) for products on market on August 8, 2016	November 8, 2018	November 8, 2018
Submission of Harmful and Potentially Harmful Constituents (HPHCs) Reports	November 8, 2019	November 8, 2019

Registration & Product Listing

- Registration and Product Listing does **not** currently apply to “foreign establishments” but only to domestic, U.S. establishments where “manufacturing activity” is occurring
- Deadline **extended to September 30, 2017** for manufacturers of deemed products marketed as of August 8, 2016

Registration & Product Listing

- Manufacturing activity means “manufacture, preparation, compounding, or processing” which includes repackaging or otherwise changing the container, wrapper, or labeling of a package
- An importer who does not own or operate “domestic establishments engaged in manufacturing tobacco products” is not subject to the registration and listing requirements

Registration & Product Listing

- FDA Unified Registration and Listing System (FURLS) – Tobacco Registration and Product Listing Module (TRLM): http://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/ucm386651.htm

- May also file Registration manually by completing Form FDA 3741a and mailing all of the necessary materials to CTP's Document Control Center

Establishment Registration

- Registration Requirements:
  - The name and full address of each establishment
  - The name and places of business of the owner or operator
  - In the case of a partnership, include the name of each partner
  - In the case of a corporation, include the name of each corporate officer and director, and the State of incorporation

Product Listing

- Must submit list of all finished products manufactured for commercial distribution at each registered facility
  - Name, use and product category
  - Product labels (required)
  - Representative sampling of advertising material and any “consumer information” (not required)
- Contract manufacturers must include information on private label brands in their product list
- Biannual report of any change to product list

Ingredient Listing

New deadlines:

- By November 8, 2017, non-small scale manufacturers must report all "ingredients" used in their finished products, including e-liquids and devices
- Small-scale manufacturers have until May 8, 2018

Ingredient Listing

- Unique Identification Based on Type of Ingredient
  - Each ingredient must be *uniquely identified*
- Info necessary to uniquely identify ingredient varies based upon **type** of ingredient
- FDA **requests** additional information, including expected functions.

Types of Ingredients

1. **Single Chemical Substance** - ingredients that are single chemical substances, e.g., nicotine, glycerin, water, propylene glycol
2. **Complex Purchased Ingredient** – mixtures of chemicals, e.g., flavors
   a. Custom Complex Purchased Ingredient - made per the manufacturer's custom specifications ("Custom CPIs"); and
   b. Commodity Complex Purchased - available as commodities or "off the shelf" raw material ("Commodity CPIs")

Single Chemical Substances

- Must be uniquely identified by using a unique scientific name or code
- Requested additional information:
  - Quality (e.g., percent purity, a published standard), any
  - Internal identification number (e.g., SKU, product code)

Complex Purchased Ingredients

- Must be identified by:
  - Manufacturer (supplier) name
  - Uniquely identifying item name/number (e.g., catalog number or UPC) used by CPI manufacturer
  - Information to uniquely identify each specified ingredient (i.e., each ingredient specified that manufacturer use) for customized ingredients
  - Requested additional information:
    - Quality (e.g., percent purity, a published standard), and
    - Internal identification number (IN)

Reporting Ingredient "Quantity"

- Quantity means unit of mass (i.e., grams) of an ingredient contained in product
- Quantity is to be expressed in terms of:
  - Unit of use for portioned product (e.g., one cigarette, one cigar) or
  - Per gram of product for a non-portioned product (e.g., container of loose snuff, reconstituted tobacco, hookah tobacco, hookah charcoal, e-liquids)

Health Document Submission

- Health documents developed between **June 23, 2009 and December 31, 2009** for deemed products on the market through August 8, 2016 must now be submitted to FDA by:
  - **February 8, 2017** for large manufacturers
  - **November 8, 2017** for small-scale manufacturers
- If have no such documents, must still notify FDA by those dates

Health Document Submission

- A “health document” broadly includes documents “related to health, toxicological, behavioral, or physiologic effects of current or future tobacco products, their constituents (including smoke constituents), ingredients, components, and additives”
- Could include analytical test reports, studies, etc. conducted on your products, but not non-product specific studies in the published literature

FURLS and eSubmitter Demonstration: Hypothetical

Hypothetical – KH Vapor Corporation

- Incorporated in Washington, DC
- Azim Chowdhury – CEO
- Manufacture open system e-cigarette
- Manufacture two e-liquid flavors – Grape and Fruit Punch
  - Fruit Punch sold in 30mL glass bottles in 0mg nicotine and 1.5mg nicotine per bottle
  - Both Fruit Punch e-liquids are also labeled for Heckman Incorporated
  - Grape sold in 30mL and 60mL glass bottles in 0mg nicotine per bottle
- Import one e-liquid (Caramel Apple) from China Vapor Corporation

Health Documents & Registration/Listing

- Can provide Health Documents (or statement that none exist) for domestic or foreign
  - KH Vapor Co. and China Vapor Co. do not have any health documents
- Only domestic establishments manufacturing products must register/list
  - Listing for Registration/Listing is not the same as ingredient listing.

Hypothetical – Product list

- E-cigarette – EC00001
- Fruit Punch, 30mL, 0mg nic – FP03000
- Fruit Punch, 30mL, 1.5mg nic – FP03015
- Fruity Heckman, 30mL, 0mg nic – HEF03000
- Fruity Heckman, 30mL, 1.5mg nic – HEF03015
- Grape, 30mL, 0mg nic – GR03000
- Grape, 60mL, 0mg nic – GR06000
- Caramel Apple, 30mL, 0mg nic – CVCA03000

Hypothetical – KH Vapor E-liquid List

SKU	30mL	60mL	0mg Nic	1.5mg Nic	Labeled KH	Labeled Heckman
FP03000	x		x		x	
FP03015	x			x	x	
HEF03000	x		x			x
HEF03015	x			x		x
GR03000	x		x		x	
GR06000		x	x		x	

Hypothetical – Vapor Device

- Components:
  - Coil
  - Mouth piece
  - Atomizer
  - Tank
  - Battery
- Ingredients
  - Coil: Stainless steel coil, silicon seal, housing, cap
  - Others (all pre-formed): mouth piece, atomizer, tank, and battery

Device “Ingredients”

Ingredient	Ingredient Type	Manufacturer	Mfg. SKU	KH Vapor Co Ingredient Number (IN)
SS Coil	Commodity CPI	Coil Co	CC1234	KH0100
Silicon Seal		Seals Inc.	SI1234	KH0101
Housing		OEM Ltd.	OEM1234	KH0102
Cap		OEM Ltd.	OEM1235	KH0103

Hypothetical – Fruit Punch E-liquid

- Components:
  - E-liquid
  - Bottle
  - Other packaging
- Ingredients
  - PG, VG, Nicotine (for 1.5mg nicotine formulation), flavor (off-the-shelf)
  - Glass bottle
  - Other packaging

Fruit Punch E-liquid Ingredients

Ingredient	Ingredient Type	Manufacturer	Mfg. SKU	KH Vapor Co Ingredient Number (IN)
PG	Single Chemical Substance	N/A	N/A	KH0001
VG		N/A	N/A	KH0002
Nicotine		N/A	N/A	KH0003
Fruit Punch Flavor	Commodity CPI	FlavorHouse	FH1234	KH0004
Bottle (30mL)		Bottle Co.	BC1234	KH0030

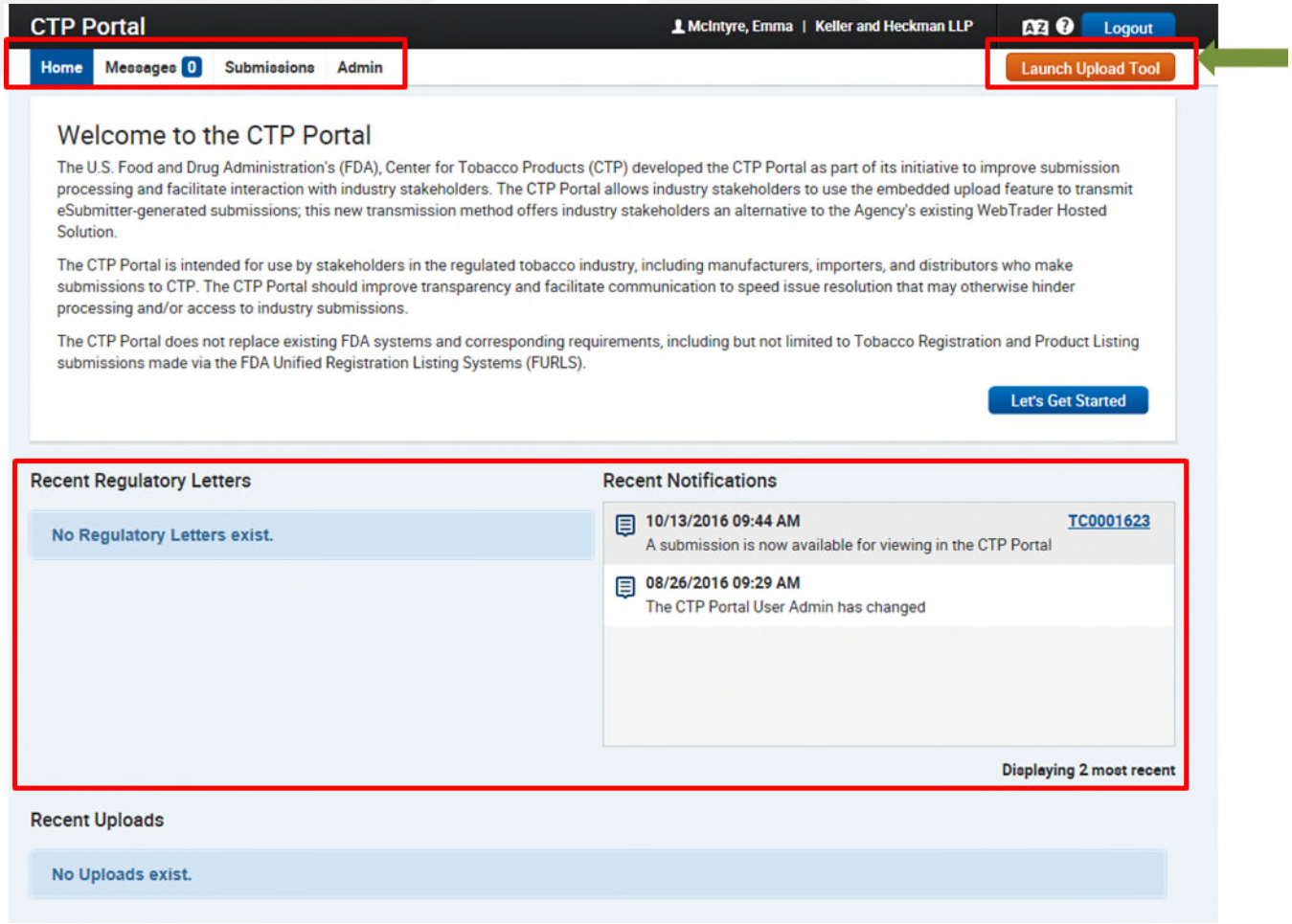
Hypothetical – Grape E-liquid

- Components:
  - E-liquid
  - Bottle
  - Other packaging
- Ingredients
  - PG, VG, flavor (made to specification)
  - Glass bottle
  - Other packaging

Grape E-liquid Ingredients

Ingredient	Ingredient Type	Manufacturer	Mfg. SKU	KH Vapor Co Ingredient Number (IN)
PG	Single Chemical	N/A	N/A	KH0001
VG		N/A	N/A	KH0002
Methyl Anthranilate		N/A	N/A	KH0005
Bottle (30mL; 60mL)	Commodity CPI	Bottle Co.	BC1234; BC1235	KH0030; KH0031
Super Grape Flavor	Custom CPI	FlavorHouse	FHcustom	KH0007

Upload Ingredient Listing to CTP Portal



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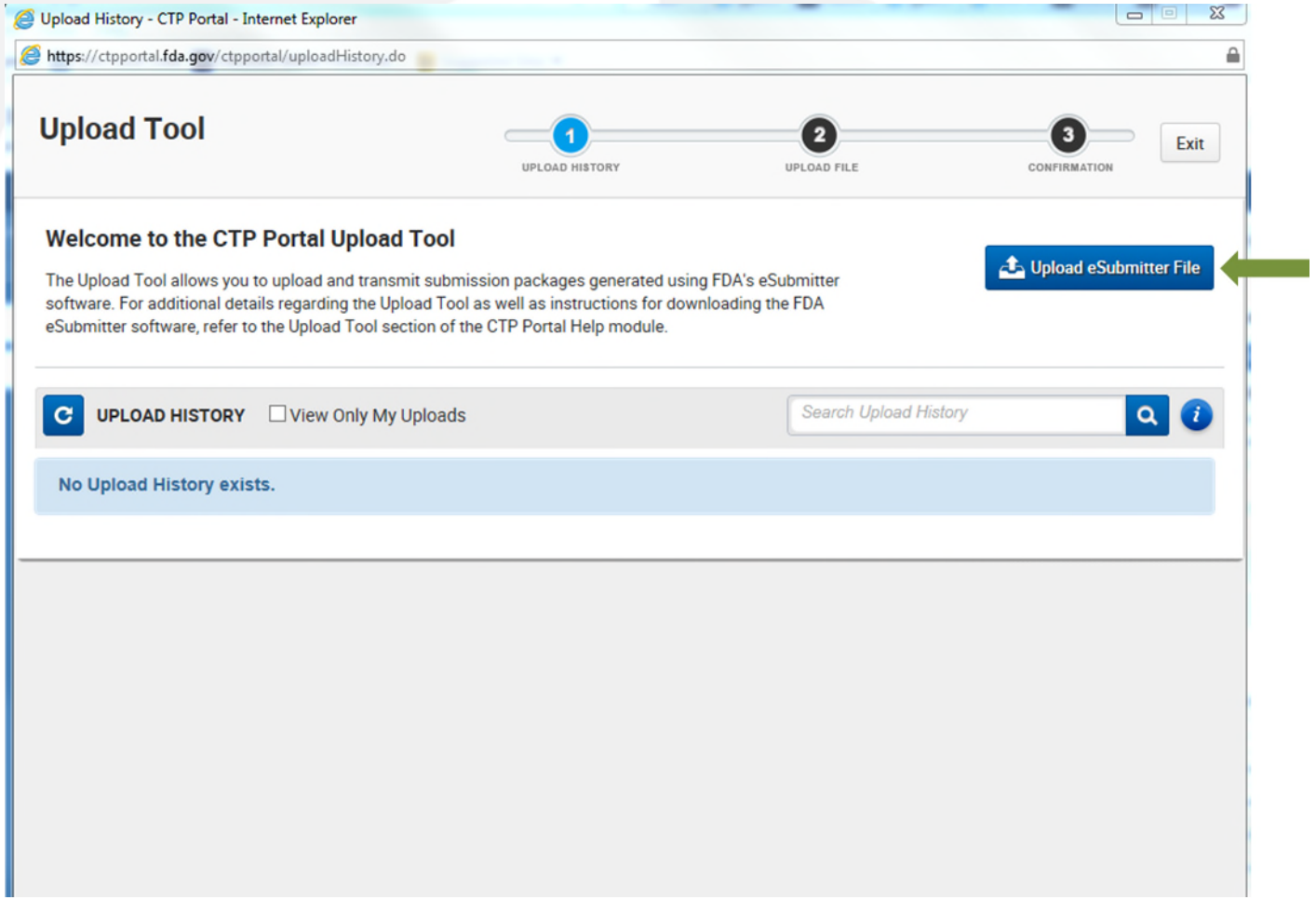

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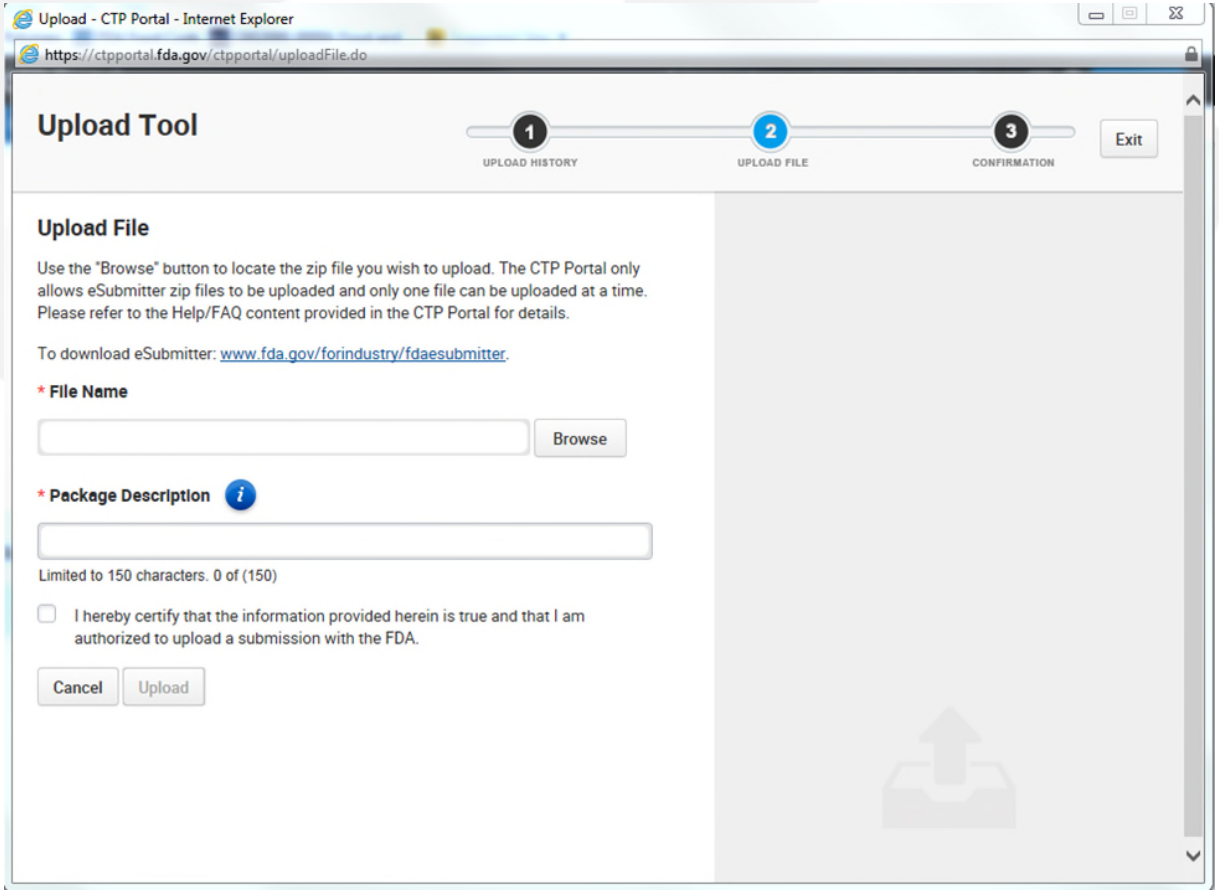

Thank you! Questions?

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