TOBACCO ENTRIES: UPDATED INFORMATION FOR FILING ENDS PRODUCTS FOR IMPORT

Importing FDA Regulated Tobacco Products

Disclaimer: This is not a formal dissemination of information by FDA and does not represent Agency position or policy.

AGENDA

- Know the Product Being Imported
- Electronic Nicotine Delivery System (ENDS)
- Information Needed for Entry Submission
- Additional Resources
- How to Contact Us?

KNOW THE PRODUCT BEING IMPORTED

KNOW THE PRODUCT BEING IMPORTED

- **Tobacco Product -** the Federal Food, Drug, and Cosmetic Act defines a “tobacco product” as “any product made or derived from tobacco, or containing nicotine from any source, that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product).”

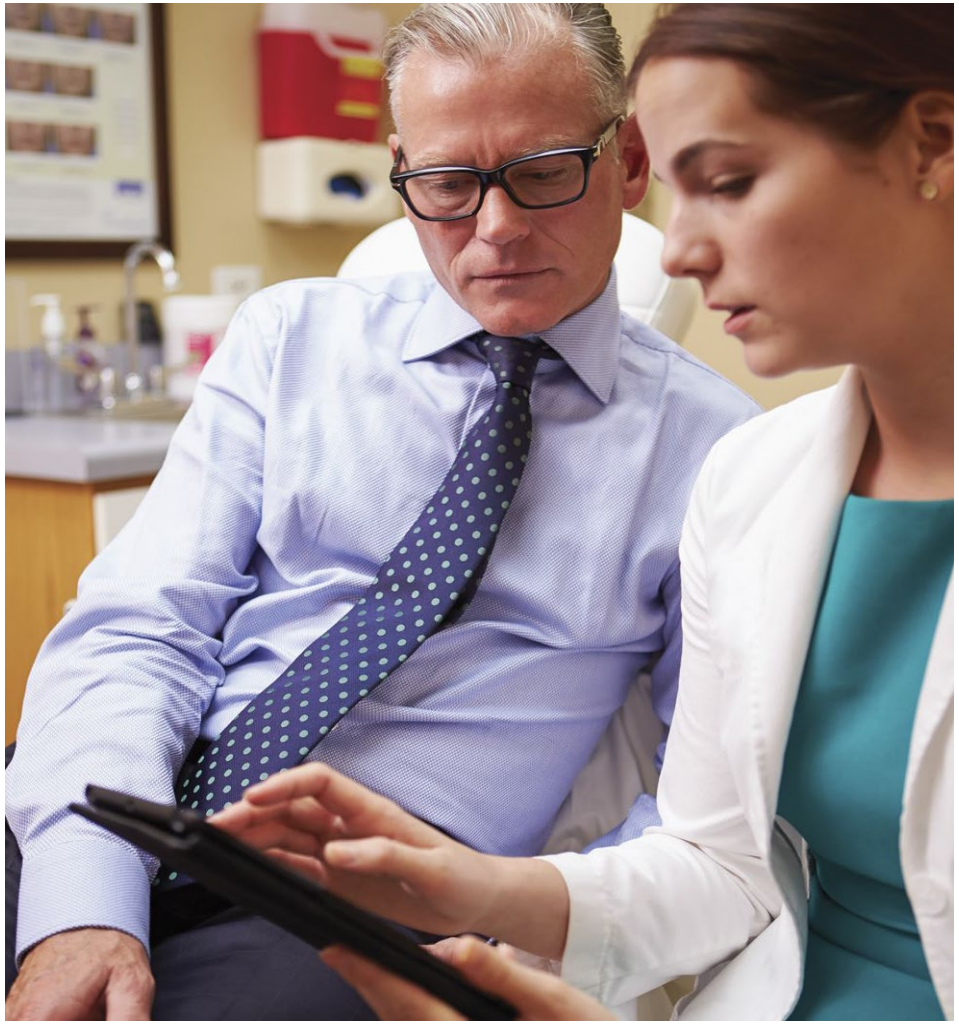
KNOW THE PRODUCT BEING IMPORTED

Examples of tobacco products -

- Cigarettes, cigarette tobacco and roll-your-own tobacco
- Smokeless tobacco (e.g. snuff and chewing tobacco)
- Electronic Nicotine Delivery Systems (ENDS)
- Cigars
- Waterpipe tobacco (e.g. hookah)
- Pipe tobacco
- Nicotine Delivery Product (e.g. lozenge, gum)
- Components and parts of tobacco products

ELECTRONIC NICOTINE DELIVERY SYSTEM (ENDS)

ELECTRONIC NICOTINE DELIVERY SYSTEMS (ENDS)



What are ENDS Products?

- Non-combustible tobacco products
- Tobacco products that use an “e-liquid” that is heated to create an aerosol
- Vapes, vaporizers, vape pens, hookah pens, electronic cigarettes (e-cigarettes or e-cigs), and e-pipes

ELECTRONIC NICOTINE DELIVERY SYSTEMS (ENDS)

Premarket Authorization Requirements -

- All new tobacco products, including new ENDS products, require FDA market authorization:
  - Premarket Tobacco Application (PMTA) Order
  - Substantial Equivalence (SE) Order
  - Exemption from Substantial Equivalence (EX) Order
- Unauthorized new tobacco products are subject to detention and refusal.

ELECTRONIC NICOTINE DELIVERY SYSTEMS (ENDS)

ENDS Enforcement Priorities -

- FDA has prioritized enforcement against the following ENDS products that lack marketing authorization:
  - Flavored, cartridge-based ENDS products
  - ENDS products without adequate measures to prevent minor's access
  - ENDS products targeted to minors
  - Certain ENDS offered for sale in the United States after 9/9/20. For example, products for which no application is pending, including those with a Marketing Denial Order and those for which no application was submitted.

What this Means for Filers-

- ✓ It is the importer's responsibility to provide **complete and accurate** information regarding premarket authorization. Failure to provide this information may cause delays in the entry review process

INFORMATION NEEDED FOR SUBMISSION

INFORMATION NEEDED FOR SUBMISSION
PROGRAM & PROCESSING CODES

Program Code for tobacco commodities is **TOB**.

The **Processing Code** will be determined by the commodity sub-type:

PG01 - Government Agency Code	Commodity Type	PG01 - Government Agency Program Code	Commodity Sub-Type	PG01 - Government Agency Processing Code
FDA	Tobacco	TOB	Consumer Use	CSU
FDA	Tobacco	TOB	For Further Manufacturing	FFM
FDA	Tobacco	TOB	Investigational	INV

INFORMATION NEEDED FOR SUBMISSION
PRODUCT CODE OVERVIEW

The FDA Product Code is seven characters long and is broken into the following five fields.

Industry	Class	Subclass	Process Indicator Code (PIC)	Product
(numeric)	(alpha or numeric)	(alpha or "-")	(alpha,numeric or "-")	(alpha or numeric)

- FDA Product Code errors are among the most common reasons for FDA Entry Rejections.
- Use a valid FDA Product Code per the FDA Product Code Builder.
- Product code is mandatory for tobacco products; Industry Code 98.

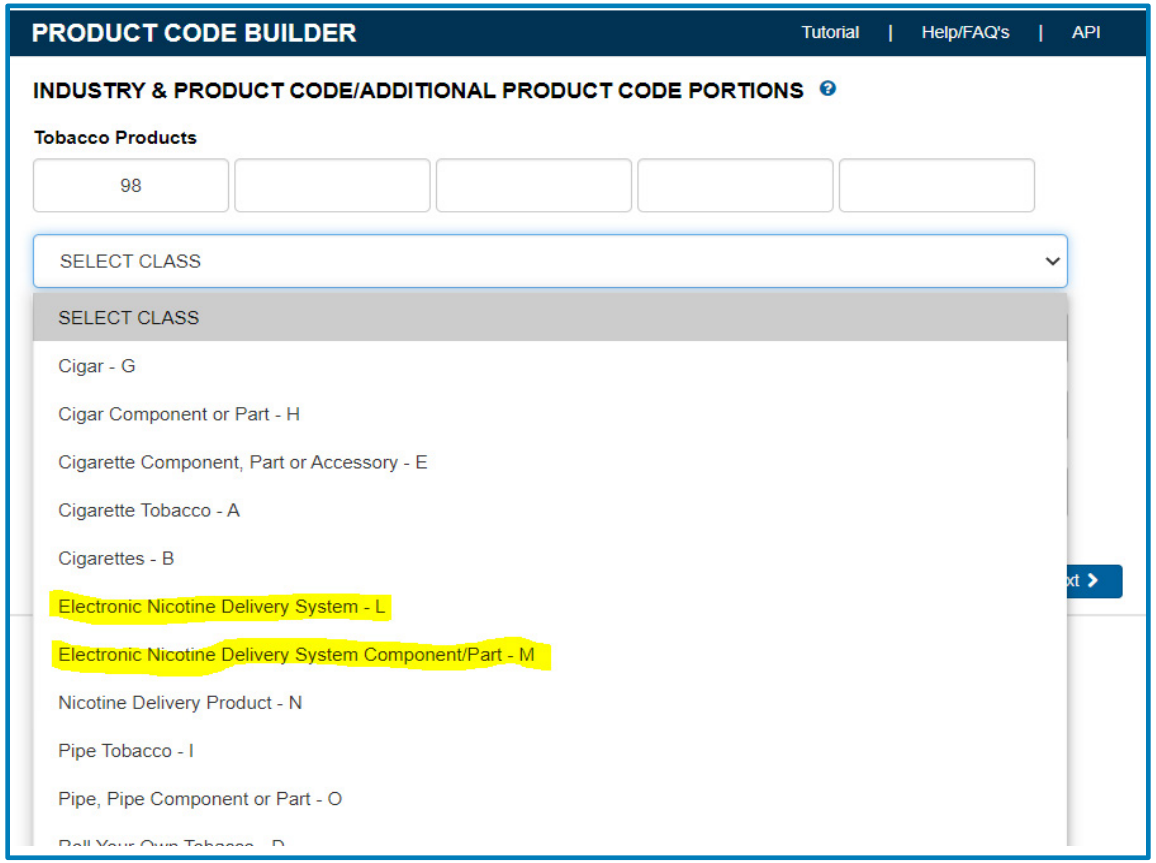
INFORMATION NEEDED FOR SUBMISSION
PRODUCT CODES

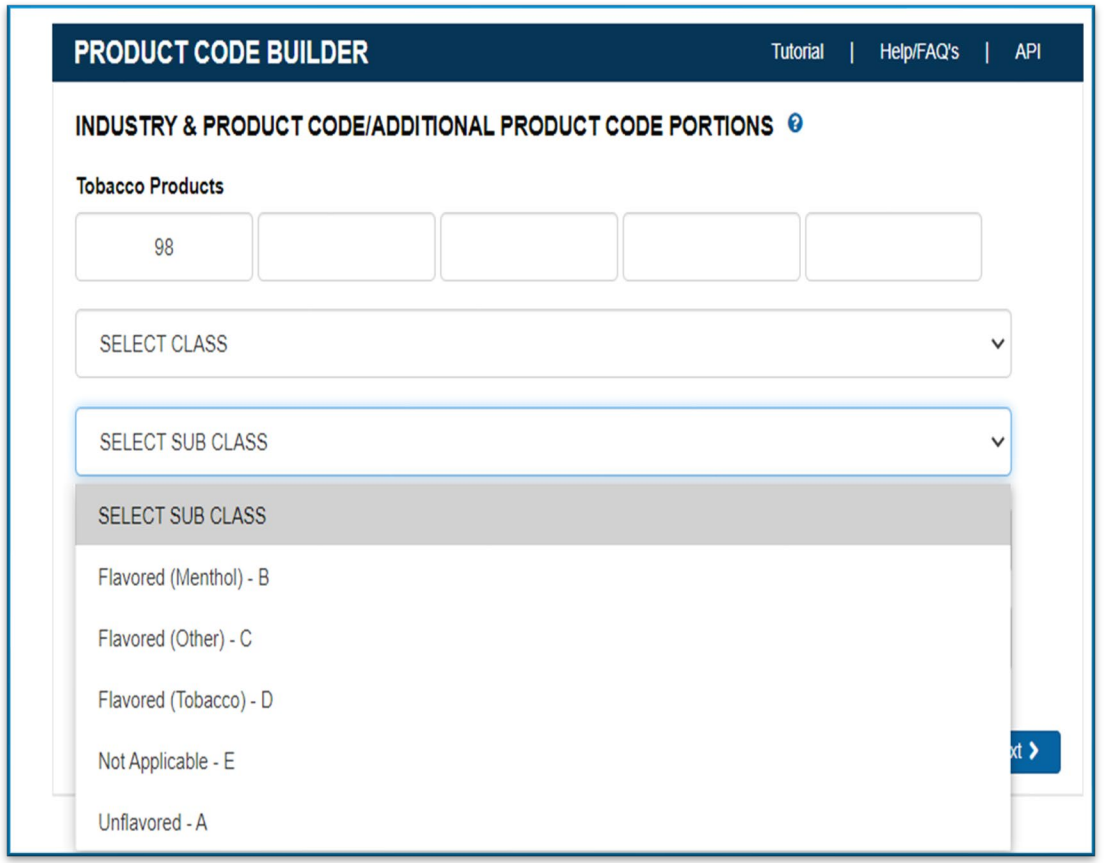
PG01: Program Code & Commodity	PG01: Processing Code & Commodity Subtype	PG02: Industry Code
TOB - Tobacco	CSU - Consumer Use	98
	FFM - For Further Manufacturing	
	INV - Investigational	

INFORMATION NEEDED FOR SUBMISSION
PRODUCT CODES

FDA

Below are the classes/subclasses used for ENDS products:





INFORMATION NEEDED FOR SUBMISSION
PRODUCT DESCRIPTIONS, PACKAGING AND CONDITION

Data Element	Necessary Information	Requirement
Commodity Characteristic Description (PG10)	In addition to common or market name, include flavor and strength of nicotine	Mandatory
Trade Name/Brand Name (PG07)	This should be the brand and sub brand of the product that is found in the marketing application	Required if the product is intended for consumer use (agency processing code CSU)
Quantity and Packaging** (if entered, the rules from the SG must be followed) (PG26)		Optional but encouraged
PGA Line Value (PG25)		Optional but highly encouraged

* New Affirmations of Compliance to be created for future use
**See FDA Supplemental Guide for ACE for valid units of measure for Tobacco Packaging Containers.

INFORMATION NEEDED FOR SUBMISSION
INTENDED USE CODES

FDA

Intended Use Codes are conditional for tobacco products.

Intended Use Code	Intended Use Description
150.000	For commercial process as non-food
155.000	For Commercial Assembly as a Non-Food Product to be consumed
180.001	For Research and Development as a non-Food Product - Animal or plant for biomedical research
180.000	For Research and Development as a non-Food Product – All other Uses
110.000	For Public Exhibition or Display as a Non-Food Product
130.000	For Consumer Use as a Non- Food Product
140.000	For Charitable Organization Use as Non-Food Product
130.037	For re-packaging and re-labelling**

INFORMATION NEEDED FOR SUBMISSION
AFFIRMATIONS OF COMPLIANCE

- Although Affirmations of Compliance are currently optional in ACE, transmitting complete and accurate information including the premarket authorization enables timely review of an entry.

Affirmations of Compliance

If Government Agency Processing Code is "CSU" and the product was not commercially marketed in the U.S. as of February 17, 2007 (CMT was not declared), then TST and one of the following should be transmitted: SE, PMT or EXE.

Code	Description	Syntax
SE -or– PMT -or- EXE	If the product was not commercially marketed in the U.S. as of February 15, 2007, then one of the following may be affirmed: SE = Substantially Equivalent Indicate SE if the product has a submitted Substantial Equivalence application with FDA	Indicator Only
	PMT= Premarket Tobacco Application Indicate PMT if the product has a submitted Premarket Tobacco application with FDA	
	EXE= Exemption from Substantial Equivalence Indicate EXE if the product has a submitted exemption from substantial equivalence with FDA	
TST	Tobacco Submission Tracking Number	PM + 7N or SE + 7N or EX + 7N Example PM1234567 SE1234567 EX1234567

Please see the FDA Supplemental Guide for ACE for all other applicable codes.

INFORMATION NEEDED FOR SUBMISSION
ORIGIN AND ARRIVAL

Data Requirement	Tobacco
Country of Production or Place of Growth or Harvested or Country of Source	Mandatory
Country of Refusal	Optional (encouraged if refused by another Country)

Anticipated Arrival Date	Mandatory
Anticipated Arrival Time	Mandatory

ENDS DATA SET EXAMPLE

PG Record	Data Element	Example
PG01	Agency Code	FDA
	Program Code	TOB
	Processing Code	CSU
	Intended Use Code	150.000
PG02	Product Code	98LCA10
PG06	Country of Production/Manufacturing	China
PG07	Trade/Brand Name	Best Ecigs, cool vapes
PG10	Invoice/Common Description* for ENDS products include flavor and strength of nicotine	Ecigarette Starter Kit Mint 20mg/5mL strength of nicotine
PG19, 20, 21	Manufacturer Name, Address, FEI (MF)	Ecigs Manufacturing, 123 Main Street, Guangzhou, Guangdong, China 1234567890
	Importer of Record Name, Address, FEI (FD1)	Best Ecigs Imports Inc. 123 Main Street, Jamaica, NY 11433 0123456789
	Shipper Name, Address, FEI (DEQ)	Ecigs Manufacturing, 123 Main Street, Guangzhou, Guangdong, China 1234567890
	Submitter, Name, Address, FEI (TB)	Ecigs Manufacturing, 123 Main Street, Guangzhou, Guangdong, China 1234567890
	Delivered to Party Name, Address, FEI (DP)	Best Ecigs Imports Inc. 123 Main Street, Jamaica, NY 11433 0123456789
	Point of Contact Name, Email Address	Best CHB, JaneDoe@bestchb.com
PG23	Affirmations of Compliance	PMT; TST PMT1234567
PG25	Line Value	$50,000
PG26	All Levels of Packaging and Quantity	100 ct, 20 bx, 3 pcs
PG30	Anticipated Arrival Date and Time	10312021; 0800

SUMMARY

- ✓ **Know the product being imported and associated requirements**
- ✓ **Understand the data elements**
- ✓ **Provide correct and accurate information**
- ✓ **Give Entry Filers the information they need**
- ✓ **Obtain all necessary information from the Importer**

NOTE: FDA will not be able to process an entry without this information. You can help expedite FDA's review of your imported product(s) by initially providing accurate and complete information and by responding quickly to requests from FDA for additional documents or information.

ADDITIONAL RESOURCES

ADDITIONAL RESOURCES - DEFINITIONS

- **Tobacco Product** – …any product made or derived from tobacco, or containing nicotine from any source, that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product)…

- **Component or Part** – any software or assembly of materials intended or reasonably expected: (1) to alter or affect the tobacco product's performance, composition, constituents, or characteristics; or (2) to be used with or for the human consumption of a tobacco product. Component or part excludes anything that is an accessory of a tobacco product

ADDITIONAL RESOURCES - DEFINITIONS

- **Electronic Nicotine Delivery System (ENDS)** – include devices, components, and/or parts that deliver aerosolized e-liquid when inhaled.
- **E-liquid** – a type of ENDS product and generally refers to liquid nicotine and nicotine-containing e-liquids.
- **New Tobacco Product** - any tobacco product… not commercially marketed in the United States as of February 15, 2007 or any modification… of a tobacco product where the modified product was commercially marketed in the United States after February 15, 2007.
- **Cartridge-based ENDS Product –** a type of ENDS product that consists of, includes, or involves a cartridge or pod that holds liquid that is to be aerosolized through product use.

ADDITIONAL RESOURCES – WEB SITES

- For more general information about tobacco products, visit https://www.fda.gov/TobaccoProducts/default.htm

- FDA's Deeming Regulations for E-Cigarettes, Cigars, and All Other Tobacco Products, visit https://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/ucm394909.htm

- FDA's Imported Tobacco web page, visit https://www.fda.gov/industry/regulated-products/imported-tobacco

ADDITIONAL RESOURCES - EXAMPLES

Example of various ENDS products. All ENDS products require FDA premarket authorization. Unauthorized new tobacco products are subject to detention and refusal.

ADDITIONAL RESOURCES - EXAMPLES

Example of various ENDS products. All ENDS products require FDA premarket authorization. Unauthorized new tobacco products are subject to detention and refusal.

ADDITIONAL RESOURCES - EXAMPLES

Example of various ENDS components and parts. All ENDS products require FDA premarket authorization. Unauthorized new tobacco products are subject to detention and refusal.

ADDITIONAL RESOURCES - EXAMPLES

Example of an ENDS product (e-liquid). All ENDS products require FDA premarket authorization. Unauthorized new tobacco products are subject to detention and refusal.

HOW TO CONTACT US?

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For ACE questions, please contact:
Email: ACE_Support@fda.hhs.gov

For general import questions, please contact:
Email: FDAImportsInquiry@fda.hhs.gov

For tobacco related questions, please contact:
Email: AskCTP@fda.hhs.gov