Office of Inspections and Investigations /OII

INFORMATION FOR SUCCESSFULLY FILING ENTRIES OF ELECTRONIC NICOTINE DELIVERY SYSTEM (ENDS) AND NICOTINE POUCH PRODUCTS

*The data elements below are not all inclusive for successful entry transmission of ENDS products in ACE.

PURPOSE

ENDS and Nicotine Pouch products offered for import into the U.S. that meet the definition of a tobacco product are regulated by the U.S. Food and Drug Administration (FDA). To avoid delay of FDA admissibility process, provide complete and accurate information for each ENDS and nicotine pouch product as part of the electronic entry.

ENDS and Nicotine Pouch products differing in any characteristic (including brand name, flavor, nicotine concentration etc.) must be declared on separate lines in an entry filed via ACE.
Your customs broker should be knowledgeable in transmitting FDA-regulated products to the FDA.

DATA ELEMENTS NEEDED FOR FDA REVIEW

(THE FDA SUPPLEMENTAL GUIDE CONTAINS ALL FILING INFORMATION FOR FDA)

GOVERNMENT AGENCY PROGRAM CODE: TOB

- Commodity Sub-Type/Gov Agency Processing Code: Consumer Use/CSU, For Further Manufacturing/FFM, Investigational/INV
- Product Code: Application - Product Code Builder
- If the product is flavored, with flavors other than tobacco or menthol, use **subclass C** of the product code.
- Trade Name/Brand Name: Include the brand and sub brand of the product that is found in the marketing application.
  For Example: Use the brand name of product, not a general term like “atomizer.”
- Product Characteristic Description: In addition to the common or market name, include the flavor and strength of nicotine.
- What is the quantity of product being shipped? (i.e. 10 pallets/40 cases/100 pieces)
- Manufacturer name and address (Manufacturer Firm Establishment Identifier (FEI) Number is optional but encouraged): This should be the manufacturing site for the products being shipped. Use this to search for the FEI associated with the facility: FEI Search Portal
- Importer name and address of the Importer (FEI is optional but encouraged)
- Customer/Deliver-to-Party (Consignee) name and address in the US (FEI is optional but encouraged)

FDA PREMARKET AUTHORIZATION REQUIREMENT

ALL NEW TOBACCO PRODUCTS, INCLUDING ENDS AND NICOTINE POUCH PRODUCTS, REQUIRE FDA PREMARKET AUTHORIZATION

Code	Description	Syntax
TST	Tobacco submission tracking number is issued by FDA/CTP for the new tobacco product identified in the FDA line. It is the Substantially Equivalent (SE), Premarket Tobacco Application (PM), or Exemption from Substantial Equivalence (EX) number.	PM + 7N or SE + 7N or EX + 7N Example PM1234567 SE1234567 EX1234567
PID	Product Identification Number is a unique number assigned by the FDA to an individual product in a marketing application.	PD+1N - 7N Example PD1 PD12

FDA CONTACTS AND RESOURCES

- FDA Supplemental Guide for ACE for full Tobacco Products requirements: FDA Supplemental Guide
- For general import operations and policy questions: Imports@fda.hhs.gov
- For questions related to individual shipments: please contact the division directly.

OTHER CONTACTS AND RESOURCES

- For tariff classification inquiries, consult the Customs Rulings Online Search System (CROSS).
- For information on how to obtain a prospective ruling on the classification of imported goods, consult the CBP website.
- The most recent version of the Harmonized Tariff Schedule of the United States is available on the U.S. International Trade Commission’s website.

*** Please share this resource with your customs broker.***

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