U.S. FOOD & DRUG ADMINISTRATION

January 2024

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

Information for successfully filing entries of Electronic Nicotine Delivery System (ENDS) Products

Purpose: ENDS 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 determination of ENDS shipments, provide the information needed to successfully and accurately file entries. ENDS products differing in any characteristic (including brand name, flavor, 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 efficient review by the FDA (The FDA Supplemental Guide contains all filing information for FDA)

1. Government Agency Program Code: TOB
2. Commodity Sub-Type/Gov Agency Processing Code: Consumer Use/CSU, For Further Manufacturing/FFM, Investigational/INV
3. Product Code: Application - Product Code Builder
   ENDS products should be transmitted under class L or M. Work with your customs broker to build the correct product code. If the **product is flavored**, use **subclass C** of the product code.
4. Commodity Characteristic Description: In addition to the common or market name, include the flavor and
5. Strength of nicotine. 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".
6. What is the quantity of product being shipped? (i.e. 10 pallets/40 cases/100 pieces)
7. 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
8. Importer name and address of the Importer (FEI is optional but encouraged)
9. Customer/Consignee (ship to) name and address or address in the US (FEI is optional but encouraged)

FDA Premarket Authorization Requirement

All new tobacco products, including new ENDS products, require FDA premarket authorization:

Code	Description	Syntax
TST	Tobacco Submission Tracking Number (STN) is issued by FDA/CTP for the new tobacco product identified in the FDA line. It is the Substantially Equivalent (SE), Premarket Tobacco Application (PMT), or Exemption from Substantial Equivalence (EX) number.	PM + 7N or SE + 7N or EX + 7N Example PM1234567 SE1234567 EX1234567

Contacts and Resources

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

Please share this resource with your customs broker.