ENDS DIRECTORY INSTRUCTIONS

Every Manufacturer that intends to sell Electronic Nicotine Delivery Systems (ENDS)[1] in the Commonwealth, whether directly or through any distributor, retailer, or similar intermediary is required to file this Certification.

This certification must be completed in English. All attachments must include a certified English translation if the original document is in a different language. Attachments must clearly indicate the section to which it corresponds.

Complete the certification form. Do not leave any required fields blank.

You must indicate whether this is an initial, annual, or supplemental certification by checking one of the blocks.

Failure to produce documentation that is requested within the certification, or requested by the Tobacco Enforcement Section during review, will result in a denial of the certification.

Fees:

No certification will be accepted for submission until payment is received and processed.

If a certification is denied for any material reason, the certification fees will not be refunded so please make sure all of your paperwork is in order, all of your statements are accurate, and all your documentation is attached.

If a manufacturer wants to resubmit a certification after its certification was denied, it will be required to pay the certification fees again when submitting the subsequent certification.

Part I: Manufacturer's Identification

Provide the name, complete address and telephone number for the company official signing this certification. Provide an email address that is designated to receive all official office communication from our Office. Also, provide the company web address. Identify factory addresses, telephone numbers and names of plant managers where the ENDS products are made. If using an outside agency to complete this certification, please identify the name of that agency.

If this is an initial certification, or if your manufacturing facilities changed location within the last certification year, upload photographs and a diagram of each factory.

[1] The term "ENDS" is used interchangeably with the statutorily defined term "electronic cigarette that contains nicotine." Please reference OAG's published FAQs for the scope of products required to be certified.

Part II: Importer Information

In the blocks provided, supply all Importer(s)' contact information. Identify factory addresses, telephone numbers and identification numbers. Do not leave any fields blank, as this will cause the certification to be rejected and returned.

Part III: General Questions for the Manufacturer

Answer the questions by checking the applicable boxes, supplying detailed explanations when indicated, and attaching required documentation.

Note: Currently, 26 U.S.C. §5713 does not require a TTB Manufacturer or Importer permit for ENDS. If a change in the law were to require such permits, copies of the permit(s) would be required.

Part IV: Brand Family Identification

Provide an electronic color copy of every brand style or promotional packaging. Include views of each side of the packaging with the UPC code clearly visible. Each time you change your packaging; add new brand styles; or, create a special, limited edition package you must submit an electronic color copy. When in doubt about packaging submission, please contact our Office for clarification. Please be sure the packaging provided is clear of any proprietary information as it will be displayed to the public on the Pennsylvania ENDS Directory of Approved Brands.

For non-nicotine-containing electronic cigarettes that bear the same brand name as electronic cigarettes that contain nicotine, you must provide a sworn statement that they do not contain nicotine. The sworn statement must be accompanied by a test performed by a domestic certified lab attesting to the absence of nicotine in such product.

Section A - Brand Styles - Using the Required Brand List template provided, indicate all styles either to be added, removed, or that will remain for the filing year. Also include the brand styles manufactured at that location. If your product is manufactured at multiple locations, please indicate the manufacturing facility or facilities in the appropriate cell for each brand style.

If you are removing a brand style, we recommend waiting a sufficient amount of time before delisting to allow retailers time to clear their inventories.

Part V: Residency Status

If your company is located outside of Pennsylvania, you must appoint a resident agent for service of process and provide the Attorney General with proof of that appointment. You must provide the agent's name, address, telephone number, and email address, and attach proof of the appointment and availability of the agent for the current year.

Additionally, if your company is located outside of the United States, each importer of cigarettes belonging to your brand families must execute a declaration accepting joint and several liability with you under the Electronic Nicotine Systems Directory Act and, if the importer is located outside of Pennsylvania, appoint a resident agent for service of process. Separate declarations must be executed by each such importer.

You must certify whether your electronic cigarettes are manufactured outside of the United States and, if so, attach the executed importer(s)' declaration form(s) and proof of the appointment of the importer(s)' resident agent(s) for service of process.

Part VI: Surety Bond Status

The bond you post must be completed on the bond form prescribed by the Attorney General. You must provide the amount of your bond, the bond number, effective date, and the surety's name, phone number, email address, and attach a copy of the bond.

The bond amount required is a minimum of $50,000. The Attorney General may require a manufacturer to furnish a bond in excess of $50,000, as necessary to ensure the manufacturer's compliance with this section.

Attach inventory counts by brand and cost for product estimated to be sold in Pennsylvania during the forthcoming year and any other relevant information to determine the potential cost to the Commonwealth of product seizure and destruction in the event of noncompliance.

Part VII: Required Documentation

You must upload one of following required documents for each brand style you are seeking to certify in the Commonwealth of Pennsylvania.

1. A marketing granted order from the FDA for the ENDS products under 21 U.S.C. § 387j.
2. An acceptance letter from the FDA which was the result of a timely filed premarket tobacco product application for the ENDS products under 21 U.S.C. § 387j.
3. A copy of a document evidencing that the application remains under review with FDA.
4. A copy of the denial order from FDA and a copy of the documentation that the denial order has been stayed or vacated by the FDA or order of court.
5. Documentation demonstrating that an additional premarket tobacco product application was not required because the brand style reflects a change to the name, brand style or packaging of another ENDS product that is covered by or has been certified under Section 206-I(b)(1)(i) or 206-I(b)(1)(ii)

E-cigarettes that do not contain nicotine, but are sold under the same brand name as an electronic cigarette that is labeled, advertised, or marketed as containing nicotine, or have been determined to contain nicotine by the Attorney General or Revenue, will not be required to submit any documentation under Part VII.

Part IX: Execution by Corporate Officer, Director or Authorized Agent

The Manufacturer must certify that it is in full compliance with all state laws and that it is a resident in the Commonwealth (or has appointed a registered agent for service of process).

The Signatory executing the Manufacturer Certification Form must be an authorized Officer or Director of the Manufacturer and is responsible for all information contained within. Questions regarding this certification may directed to the designee. The Signatory's name, title, email address and telephone number must be completed.

Definitions:

(a) "electronic cigarette that contains nicotine" - An electronic cigarette that is:

a. 1. Labeled, advertised or marketed as containing nicotine; or
b. 2. Determined by the Department or the Attorney General to contain nicotine; or
c. 3. Sold under the same brand name as an electronic cigarette that contains nicotine.

Electronic cigarettes are also commonly referred to as "vapes," "e-cigarettes" and "electronic nicotine delivery systems (ENDS)."

An e-cigarette that does not contain nicotine will be required to be included on the certification and listed on the directory if it is sold under the same brand name as an electronic cigarette that is labeled, advertised, or marketed as containing nicotine, or otherwise determined to contain nicotine by the Attorney General or Department of Revenue. Manufacturers are required to certify that such electronic cigarettes do not contain nicotine if they are sold under the same brand name as one that does. They are also required to provide a test from a domestic certified lab attesting to the absence of nicotine in the product.

(b) "brand family" - all styles of an e-cigarette sold under the same trademark and differentiated from another style by means of additional modifiers or descriptors. The term includes any brand name used alone or in conjunction with any other word, trademark, logo, symbol, motto, selling message, recognizable pattern of colors or any other indicia of product identification identical or similar to or identifiable with a previously known brand of electronic cigarette that contain nicotine.

(c) " brand style" - a variety of an e-cigarette family that is differentiated from other brand styles within a brand family by additional modifiers or descriptors.

Brand styles may be differentiated by factors including but not limited to color, flavor, nicotine strength, size, shape, capacity, quantity, the presence or lack of a certain ingredient, stock keeping unit number, or FDA submission tracking number.

(d) "contraband" - Any electronic cigarette that contains nicotine for retail sale in this Commonwealth which is either not listed or is removed from the directory in violation of section 206-I; or any tobacco product for which state excise tax imposed by Article XII-A of the Tax Reform Code of 1971 has not been paid; or any tobacco product sold, offered, distributed or possessed for sale and tobacco products acquired, held, owned, possessed, transported, imported or caused to be imported that the person knows or should know are intended for retail distribution or retail sale in this Commonwealth in violation of the Tax Reform Code of 1971. The term includes tobacco products which have been seized by the Commonwealth and for which property rights no longer exist under Article [cite] of the Fiscal Code.

(e) "timely filed premarket tobacco product application" - A timely filed premarket tobacco product application (PMTA) requires: (1) An application under 21 U.S.C. § 387j (relating to application for review of certain tobacco products) for an electronic cigarette that contains nicotine derived from tobacco, (2) The electronic cigarette that contains nicotine must have been marketed in the United States as of August 8, 2016, (3) The application was submitted to the U.S. Food and Drug Administration (FDA) on or before September 9, 2020, and (4) Accepted for filling by the FDA.