

Frequently Asked Questions

1) The finished ENDS products I am filing for importation do not have marketing authorization. Can the tobacco products without marketing authorization be imported into the U.S. to be sold and/or distributed?

Short Answer– All imported new finished tobacco products, including new finished ENDS products, on the market without the statutorily required [premarket authorization](#) are marketed unlawfully. Unauthorized new finished tobacco products offered for import into the US may be detained or refused admission.

Currently, new tobacco products for which no application is pending, including, for example, those with a Marketing Denial Order and those for which no application was submitted, are among FDA’s highest enforcement priorities.

As a reminder, new tobacco product means (1) any tobacco product (including those products in test markets) that was not commercially marketed in the United States as of February 15, 2007; or (2) any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient) of a tobacco product where the modified product was commercially marketed in the United States after February 15, 2007. See section 910(a) of the FD&C Act.

In addition, a finished tobacco product refers to a tobacco product, including all components and parts, sealed in final packaging intended for consumer use (e.g., filters or filter tubes sold separately to consumers or as part of kits).

2) Has there been a change to ENDS import requirements?

Short Answer- No, all imported new finished tobacco products, including new finished ENDS products, require FDA marketing authorization to be legally sold and/or distributed in the US. Filers are reminded to transmit complete and accurate information regarding their product’s market authorization status.

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3) In the past, I did not transmit information regarding marketing authorization when importing my ENDS products but still received an FDA Release for my imported tobacco products. Will my ENDS lines be processed the same?

Short Answer –FDA needs information regarding a tobacco product’s marketing authorization status to process an entry offered for importation into the US. You can help expedite FDA’s review of your tobacco product(s) by initially providing accurate and complete information and by responding quickly to requests from the FDA for additional documents or information. As a reminder, unauthorized new finished tobacco products offered for import into the US – including unauthorized new finished ENDS products - may be detained or refused admission.

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4) I do not know the marketing authorization status for the ENDS products I broker and/or import. What should I do?

Short Answer – It is the importer of record’s responsibility to provide complete and accurate information to FDA regarding the marketing authorization status of a tobacco product offered for import into the US. Contact the importer of record and obtain this information before filing an entry. As a reminder, unauthorized new finished tobacco products offered for import into the US – including unauthorized new finished ENDS products - may be detained or refused admission.

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5) The ENDS products I import are made with non-tobacco nicotine (NTN) (examples: tobacco-free nicotine, synthetic nicotine). Do the same requirements apply to my products?

Short Answer – Yes, on March 15, 2022, President Biden signed H.R. 2471 – the Consolidated Appropriations Act, 2022. As a result, the FD&C Act now includes specific language that makes clear that FDA regulates tobacco products containing nicotine from any source. As of April 14, 2022, manufacturers, distributors, importers and retailers of tobacco products containing non-tobacco nicotine (NTN) must ensure compliance with applicable requirements under the Federal Food, Drug, and Cosmetic Act (FD&C Act) resulting from this law.

All imported new finished tobacco products, including new finished ENDS products that are made with non-tobacco nicotine, require FDA marketing authorization to be legally sold and/or distributed in the US. Filers are reminded to transmit complete and accurate information regarding their product's market authorization status.

Importers of NTN products who wish to market their products are required to submit a premarket application and obtain FDA authorization to market their product, or they will be subject to FDA enforcement; the deadline for premarket application submissions for NTN products was May 14, 2022.

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