CENTER FOR TOBACCO PRODUCTS

March 31, 2023

Ms. Deanna D. Clark, Esq.
Clark-Esposito Law Firm, P.C.
Counsel to Vapor Vapes, Inc.
1345 Avenue of the Americas, Fl 33
New York, NY 10105

Re: Docket FDA-2022-P-2483

Dear Ms. Clark:

This is a tentative response to inform you that the Food and Drug Administration (FDA) does not yet have a final response to your citizen petition received on October 6, 2022, and submitted on behalf of Vapor Vapes, Inc.

Your petition requests FDA to take the following actions:

> (1) amend[] the regulation pertaining to the export of tobacco products, namely, 21 C.F.R. §1.101(b), (2) issue a Guidance document for industry for Tobacco Product Inspections at manufacturing facilities that are engaged, in whole or in part, in the manufacture of tobacco products for export, and (3) issue an update to FDA's Investigations Operations Manual (IOM) regarding inspections of manufacturers that export a tobacco product.

In accordance with Title 21 Code of Federal Regulations Section 10.30(e)(2)(iv), this letter is to advise you that we were not able to reach a decision on your petition within the first 180 days of its receipt because of other agency priorities. We will continue to review the issues raised and complete our review of your petition in the context of other program priorities within the Center for Tobacco Products.

Regards,

May D. Nelson
Director, Office of Regulations
Center for Tobacco Products
Food and Drug Administration