Date

Dr. Norman E. Sharpless

Acting Commissioner

Food and Drug Administration

10903 New Hampshire Avenue

Silver Spring, MD 20993

Docket No. FDA-2019-D-0661, Modifications to Compliance Policy for Certain Deemed Tobacco Products

Dear Acting Commissioner Sharpless:

I am writing to submit comments on the modifications to the FDA’s compliance policy on flavored electronic cigarettes and flavored cigars.

*INSERT BACKGROUND ON YOU AND YOUR COMPANY:*

*• How many people do you employ?*

*• How much tax revenue do you generate?*

*• What percentage of your sales come from tobacco products (approx. or % is fine)*

*• What percentage of your sales come from e-cigarettes? (approx. or % is fine)*

(Your business name) is a member of the Convenience Distribution Association, which is the trade organization working on behalf of convenience products distributors in the United States. Associate members include leading convenience product manufacturers, brokers, suppliers and others allied to the industry. Convenience distributors employ nearly 59,000 people directly and support over 173,000 jobs nationally. The industry has an overall business impact of $102 billion, including collecting $2.3 billion in taxes at the federal, state and local level and over $30 billion in federal, state and local excise tax.

*Suggested comments or topics on the proposed changes to the FDA compliance policies regarding electronic cigarettes/vapor products and flavored cigars are as follows (remember to use your own words; you can also add other comments you feel are appropriate):*

Allowing the sale of only tobacco, menthol and mint flavored electronic cigarettes/vapor products in all stores while at the same time permitting the sale of other flavored electronic cigarettes only in age-restricted stores is not reasonable and restricts the ability of adults to purchase the flavored electronic cigarettes of their choice. Retailers that allow minors to enter their stores are responsible business people.

The vast majority of retailers comply with the law and prevent the sale of tobacco products, including electronic cigarettes, to underage youth. This Guidance penalizes these law-abiding retailers because a significant majority of underage youth are resourceful in obtaining electronic cigarettes through non-retail, social sources (older friends, siblings and even parents). Banning the sale of other flavored electronic cigarettes and vapor products in convenience stores, service stations, grocery stores and drug stores will not solve the social sources issues and is unnecessary and overreaching.

FDA’s own research shows that our industry’s policies are effective. The Center for Disease Control and Prevention’s 2017 Youth Risk Behavior Surveillance System found that 86.4% of students who used e-cigarettes did not get them from stores—they get them from adults over 18 or the Internet. Likewise, 2016 data from the FDA’s Population Assessment of Tobacco and Health (PATH) study found that 86.1% of underage individuals who had used e-cigarettes in the past 30 days did not get them from a store. Of those youths that did get e-cigarettes from a store, the study shows that 76% of them got the products from a vape shop. These studies show that banning the sale of flavored e-cigarettes will not keep underage individuals from using these products. Instead, FDA is expanding the market for retailers—like vape shops and online retailers—that are less likely to properly verify the age of their customers than in convenience stores.

The August 2018 study from the American Journal of Health Promotion, cited by FDA at footnote 28 of the draft guidance, shows clearly that businesses in my industry do a better job preventing sales of e-cigarettes to minors than do adult-only stores and Internet sellers. That data shows that 32.2% of the retail purchases of e-cigarettes by minors were bought from Internet sellers, 22.3% were bought from vape shops, and 16.4% were bought from tobacco stores while only 5.6% were bought from my industry, convenience stores. There are more than 150,000 convenience stores across the country and about 10,000 vape shops and tobacco stores combined. That means, according to the American Journal of Health Promotion study, each vape shop/tobacco stores is on average more than 100 times as likely to sell an e-cigarette to minor than a convenience store. There is no justification then for FDA to focus enforcement on stores like convenience stores that allow minors to enter rather than stores like vape shops and tobacco stores that are supposedly adult-only.

The federal law that authorizes the FDA to regulate tobacco products also prohibits the agency from banning the sale of a particular kind of tobacco product in a specific kind of store. However, this is what the FDA is proposing to do by not allowing many different flavored electronic cigarettes and vapor products to be sold in stores that minors can enter.

The FDA is proposing to remove from the market numerous flavored cigars that were introduced in the marketplace between February 15, 2007 and August 8, 2016. Congress put restraints on the FDA by not allowing the agency to ban the sale of an entire category of a tobacco product. The proposed Guidance is essentially banning the sale of all flavored cigars throughout the country even though Congress prohibited the agency from taking this kind of action.

Many adult tobacco users have transitioned to non-combustible tobacco products or electronic cigarettes and vapor products, which can represent a reduced harm compared to traditional combustible tobacco products. In addition, studies have found that adults have used e-cigarettes and vapor products to quit smoking altogether. One reason for this transition and use of e-cigarettes and vapor products is the availability of different flavored products. Restricting or prohibiting flavors may cause adults to continue to use, or return to using, other combustible tobacco products.

Restrictions or bans on the sale of flavored electronic cigarettes and flavored cigars will create an opportunity for the illegal sale of these flavored tobacco products. An illicit marketplace will develop to satisfy the demand of adult consumers for flavored tobacco products. Moreover, criminal elements that sell these flavored tobacco products would not be concerned with verifying the legal age of individuals, which could allow underage youth to have more easy access to electronic cigarettes and flavored cigars.

If an illegal market for flavored tobacco products occurs, the legal retail sale of these flavored tobacco products could decline significantly. This decline in legal sales will reduce the amount of federal and state cigarette and tobacco product excise taxes plus decrease the amount of state sales tax collected.

The FDA does not offer any scientific evidence that restricting the sale of other flavored electronic cigarettes to minimize youth access to these products would result in these same youths beginning to use flavored cigars. Without any scientific data, the FDA cannot claim that restricting electronic cigarette sales justifies banning all flavored cigar products from the marketplace.

A federal agency guidance document is supposed to interpret current law and provide the agency’s thinking on how a law will be administered and enforced. However, the proposed FDA Guidance document goes much further and, in reality, is attempting to adopt new regulations by restricting where certain flavored electronic cigarettes can be sold and removing numerous flavored cigar products from the market. The Guidance document cannot be used by the FDA as a substitute for proposing a new regulation or prohibition.

Thank you for the opportunity to submit comments about the proposed Guidance document.