



June 16, 2020

Stephen Hahn
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Hahn:

We write today to seek your help in getting transparency from the U.S. Food and Drug Administration (FDA) regarding the legal status of certain tobacco products. Without this needed transparency, regulated businesses will have no way to know which products are legal and which are illegal.

By way of background, the National Association of Convenience Stores (NACS) and the Society of Independent Gasoline Marketers of America (SIGMA) represent the convenience and fuel retail and distribution industries.¹ The industry NACS and SIGMA represents employs 2.3 million workers and generates more than \$650 billion in total sales, representing more than 3 percent of U.S. Gross Domestic Product. Because of the number of fuel and other transactions in which the industry engages, fuel retailers and marketers handle approximately one of every 30 dollars spent in the United States. Convenience stores serve about 160 million people per day—around half of the U.S. population. Nevertheless, the convenience store and fuel retail industry is truly an industry of small businesses. Approximately 63 percent of convenience store owners operate a single store. Tobacco products constitute about one third of in-store sales in the industry.

On September 9, 2020, manufacturers of tobacco products such as e-cigarette and vapor products that were not on the market prior to the predicate date in the Tobacco Control Act must submit pre-market approval applications to FDA for their products to remain on the market. Products for which an application is submitted by the deadline can remain on the market for up to one year or until their application is decided.

¹ NACS, the leading global trade association dedicated to advancing convenience and fuel retailing, serves as a trusted advisor to over 1,500 retailer and 1,600 supplier members from more than 50 countries. SIGMA represents a diverse membership of approximately 260 independent chain retailers and marketers of motor fuel.

Retailers of these products are preparing their compliance plans for this upcoming deadline. But, these retailers have a concern that they might not know how to comply with these new restrictions. That is because only FDA will know which manufacturers have submitted pre-market approval applications and for which products those applications were filed. Each manufacturer will know the products for which it filed an application, but any manufacturer willing to continue selling its product after the deadline will undoubtedly represent that it has filed the necessary application.

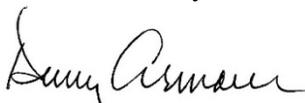
Retailers (and wholesalers) of these products will only know with any confidence which products can remain on the market after September 9th if FDA informs them of this fact. Our industry is concerned, however, because FDA has not said that it will provide any information about which products are legal or illegal to sell after that deadline or which manufacturers have filed applications for which products. Unless the FDA commits to informing the regulated community of what tobacco products are legal to sell, regulated businesses will not be able to comply with the law.

This is an urgent problem. Without the FDA's help, the industry faces the prospect of unwitting noncompliance and serious regulatory penalties from the FDA based on secret information that its members cannot know. That is completely inconsistent with American notions of good government and due process of law.

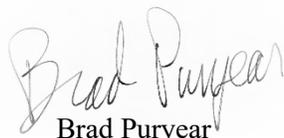
We ask you in the strongest terms to rectify this problem promptly and commit that FDA will have a clear, orderly process for informing the regulated community which tobacco products are or are not legal to sell following the September 9th pre-market approval deadline.

Thank you for your attention to this pressing issue.

Sincerely,



Henry Armour, Ph.D.
President & CEO
NACS



Brad Puryear
President
SIGMA