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Norman E. Sharpless
Acting Commissioner
Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

RE: Tobacco Products; Required Warnings for Cigarette Packages and Advertisements
[Docket No. FDA-2019-N-3065]

Dear Commissioner Sharpless:

On behalf of our clients, the National Association of Convenience Stores (“NACS”) and the Society of Independent Gasoline Marketers of America (“SIGMA”) (collectively “the Associations”), we appreciate this opportunity to provide comments on the Food and Drug Administration’s (“FDA” or the “Agency”) proposed rule establishing new required cigarette health warnings for cigarette packages and advertisements.¹ These comments are intended to ensure the Agency understands the Proposed Rule’s burden on retailers who receive cigarette packages and advertisements from tobacco product manufacturers, importers, and/or distributors. Requiring retailers to submit a plan to FDA that outlines how they will randomly and equally display the required warnings on cigarette packaging and how they will quarterly rotate the required warnings in cigarette advertising unduly burdens the retailer and is not achievable.² As such, FDA should revise the Proposed Rule to clarify that these marketing plan requirements do not apply to retailers.

I. Background on the Associations

The convenience and petroleum retailing industry has become a fixture in American society and a critical component of the nation’s economy.³ In 2018, the fuel wholesaling and

¹ Dep’t Of Health And Human Services, Food and Drug Administration; *Tobacco Products; Required Warnings for Cigarette Packages and Advertisements*; 84 Fed. Reg. 159 (Aug. 16, 2019) available at <https://www.govinfo.gov/content/pkg/FR-2019-08-16/pdf/2019-17481.pdf> [hereinafter “Proposed Rule”].

² *Id.* at § 1141.10(g).

³ NACS is an international trade association representing the convenience store industry with more than 2,100

convenience industry employed more than 2.375 million workers and generated \$654.3 billion in total sales, representing more than 3 percent of U.S. Gross Domestic Product.⁴ 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—and the industry processes over 75 billion payment transactions per year. 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.

II. Retailer Exemptions in the Tobacco Control Act

Congress, when it passed the Family Smoking Prevention and Tobacco Control Act (“Tobacco Control Act”)⁵ in 2009, granted FDA the authority to regulate tobacco products to reduce their use and prevent their uptake by underage children. The Tobacco Control Act included provisions that require graphic health warnings on all cigarette packages and advertisements.

The Tobacco Control Act, however, contains exemptions for retailers with regard to the graphic health warnings on cigarette packages and advertisements. Specifically, retailers are exempt from the graphic health warnings requirements if they sell or display certain non-compliant cigarette packages or advertisements that are supplied to them by a tobacco product manufacturer, importer, or distributor as long as the packages: (1) contain a graphic health warning; (2) are not created by or on behalf of the retailer (and the retailer is not otherwise responsible for including the required warning); and (3) are not altered by the retailer in a material way.⁶ A similar rule applies for advertisements.⁷ Those requirements only apply to retailers that direct the warning statements (such as when they create the advertisements) or alter them.

The Associations appreciate that FDA recognizes these exemptions in many sections of the Proposed Rule. For example, the Proposed Rule clearly states that retailers are not in violation of this rule as long as the cigarette packages: (1) contain a graphic health warning, (2) are supplied by a licensed tobacco product manufacturer or distributor, and (3) have not been altered by the

retailer and 1,750 supplier companies as members, the majority of whom are based in the United States. SIGMA represents a diverse membership of approximately 260 independent chain retailers and marketers of motor fuel.

⁴ All data in Section I comes from the NACS, State of the Industry Annual Report of 2018 Data (June 2019).

⁵ Pub. L. 111-31 (2009); 123 Stat. 1776.

⁶ *Supra* 5 at Section 201(a)(4). (“A retailer of cigarettes shall not be in violation of this subsection for packaging that contains a warning label; is supplied to the retailer by a license- or permit-holding tobacco product manufacturer, importer, or distributor; and is not altered by the retailer in a way that is material to the requirements of this subsection.”)

⁷ *Supra* 5 at Section 201(c)(4). (“This subsection and subsection (b) apply to a retailer only if that retailer is responsible for or directs the label statements required under this section except that this paragraph shall not relieve a retailer of liability if the retailer displays, in a location open to the public, an advertisement that does not contain a warning label or has been altered by the retailer in a way that is material to the requirements of this subsection and subsection (b).”)

retailer.⁸ Moreover, FDA makes clear that the advertisement provisions in Section 1141.10(d) of the Proposed Rule only apply to a retailer if that retailer creates the advertisements (as long as the advertisement has a graphic health warning and has not been altered by the retailer).⁹ Unfortunately, FDA does not make the same distinction with regard to the marketing plan requirements found in Section 1141.10(g) of the Proposed Rule. That oversight conflicts with and exceeds the boundaries of FDA's statutory powers granted by the Tobacco Control Act.¹⁰

III. Concerns with Proposed Rule's Marketing Plan Requirements

The Associations are concerned with the marketing plan requirements found in the Proposed Rule.¹¹

A. Plan for Required Warnings for Cigarette Packages

The Proposed Rule requires that retailers submit a plan to FDA on how the health warnings will be displayed an equal number of times on each product and distributed randomly and equally across the country.¹² The Associations' members receive the cigarette packages that they sell from tobacco product manufacturers or distributors. As such, retailers have no control over which health warning is displayed on the cigarette package and are unable to draft a plan to implement these requirements. Moreover, there is no way for a retailer to dictate how the cigarette warnings will be equally distributed on each brand of the tobacco products or how the health warnings will be randomly and equally distributed in all areas of the United States since retailers do not manufacture or distribute the products.

Even if retailers had the ability to track warnings across numerous different products from numerous manufacturers, it is not clear how FDA wants those warnings to be distributed. Must there be balance of warnings by brand, manufacturer, distributor, individual retail location, across the retail chain, or otherwise? The proposed rule does not explain what FDA expects to happen. For example, if two separate brands of cigarettes send a product to a convenience store owner with the same health warning, is that retailer required to return the tobacco product and ask for a new one with a different health warning? That level of tracking is not possible given that the retailer has no control over the specific items they receive. Retailers should not be required to submit a marketing plan for warnings on cigarette packages and requiring retailers to do so violates the Tobacco Control Act. The Proposed Rule should be revised to clearly limit these requirements to tobacco product manufacturers and distributors.

⁸ *Supra* 1 at § 1141.1(c).

⁹ *Supra* 1 at § 1141.1(d).

¹⁰ The requirements imposed on retailers in the Proposed Rule also raise serious First Amendment problems due to the speech FDA is forcing retailers to engage in. Many retailers disagree with some of the messaging included in graphic warnings and significant parts of that messaging are false and/or give viewers a false impression. Those problems run afoul of retailers' First Amendment protections.

¹¹ *Supra* 1 at § 1141.10(g).

¹² *Supra* 1 at § 1141.10(g)(1).

B. Plan for Rotation of Health Warnings on Advertisements

The Proposed Rule also requires retailers submit a plan that explains how they will rotate advertisements for each brand of cigarette on a quarterly basis so that there is a new health warning displayed.¹³ Many tobacco product advertisements are not created by the retailer. Instead, tobacco product manufacturers often create advertisements and provide them to the retailer to display. As such, retailers cannot submit a plan for the rotation of health warnings on advertisements that they will have the ability to follow. Any obligation must be placed on the entity that creates the advertisement.

As long as the tobacco product manufacturer or other entity that is responsible for the advertisement has a plan to rotate the health warnings on advertisements and supplies those advertisements to the retailer, that should satisfy FDA's concerns. And, as with warnings on packaging, requiring retailers to submit such plans exceeds FDA's statutory authority.

FDA should revise the Proposed Rule to include the retailer exemption for advertisements that is found in the Tobacco Control Act.¹⁴ A retailer should only be obligated to submit a marketing plan to FDA for the advertisements that retailer creates itself.

IV. Conclusion

The Associations appreciate this opportunity to present their views on the impact the Proposed Rule will have on the retail community. As FDA finalizes the Proposed Rule, the Agency should clarify the marketing plan provisions found in Section 1141.10(g) that require a plan to randomly and equally display the required health warnings on cigarette packaging and quarterly rotate the required health warnings in cigarette advertising. These requirements, including submitting a plan to FDA, should follow the language of the Tobacco Control Act and should not apply to retailers that receive these items from tobacco product manufacturers and/or distributors.

Sincerely,



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¹³ *Supra* 1 at § 1141.10(g)(2).

¹⁴ *Supra* 5 at Section 201(c)(4). (“This subsection and subsection (b) apply to a retailer only if that retailer is responsible for or directs the label statements required under this section except that this paragraph shall not relieve a retailer of liability if the retailer displays, in a location open to the public, an advertisement that does not contain a warning label or has been altered by the retailer in a way that is material to the requirements of this subsection and subsection (b).”)