



September 12, 2018

Reynolds American Inc.  
401 N. Main Street  
Winston Salem, N.C. 27101

Dear Mr. Mike Ogden:

Your company is currently marketing Vuse, an electronic nicotine delivery system (ENDS) product, which is subject to regulation by the Food and Drug Administration (FDA or the agency) pursuant to Section 901(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Family Smoking Prevention and Tobacco Control Act of 2009 (TCA), and associated regulations. This includes the requirement that a “new tobacco product” undergo premarket review and receive authorization from FDA permitting the product’s sale and distribution prior to being offered or delivered for sale into interstate commerce.<sup>1</sup> In May 2016, when FDA issued the regulation deeming ENDS products subject to FDA’s tobacco authorities, the Agency announced that, as an exercise of enforcement discretion, it intended to defer enforcement of the premarket review requirement for certain ENDS, setting a compliance date of August 8, 2018, for submission of premarket tobacco product applications (PMTAs) for newly deemed finished tobacco products that were on the market as of August 8, 2016.<sup>2</sup> In August 2017, FDA announced that, as part of its comprehensive plan for tobacco and nicotine regulation, it would exercise enforcement discretion to extend the premarket review compliance dates for this category of noncombustible tobacco products until August 8, 2022.<sup>3</sup> This compliance policy does not apply to any new tobacco product that was not on the market as of August 8, 2016.

As described below, FDA is reevaluating its current compliance policy with respect to Vuse brand products and similar products. We request that you respond to this letter as directed. Failure to respond may result in FDA taking action to enforce the premarket authorities in the TCA with respect to Vuse products, including the authority to take action against products that are adulterated within the meaning of section 902(a)(6) of the FD&C Act in that they are required by section 910(a) to have premarket review and do not have an order in effect under 910(c)(1)(A)(i).

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<sup>1</sup> FD&C Act § 910(a)(2)(A), (c).

<sup>2</sup> 81 Fed. Reg. 28974, 28978 (May 10, 2016).

<sup>3</sup> *Guidance for Industry: Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule (Revised)* (August 2017), available at

<https://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM557716.pdf>.

## Background

FDA prohibits the sale and distribution of tobacco products to minors.<sup>4</sup> In enacting the TCA, Congress expressed concern that an “overwhelming majority of Americans who use tobacco products begin using such products while they are minors and become addicted to the nicotine in those products before reaching the age of 18” and that “the use of tobacco products by the Nation’s children is a pediatric disease of considerable proportions that results in new generations of tobacco-dependent children and adults.”<sup>5</sup> In 2016, the final deeming rule extended the agency’s tobacco authorities to additional tobacco products, including ENDS.<sup>6</sup> During the rulemaking process, and since, FDA carefully considered the public health implications of a compliance policy regarding the requirement to obtain premarket authorization for deemed tobacco products that are “new tobacco products.” In the preamble to the final rule, FDA announced compliance dates intended to balance concerns about the extended availability of such products without scientific review; concerns regarding flavored tobacco products’ appeal to youth; and emerging evidence that some adults may potentially use certain flavored tobacco products to transition away from combusted tobacco use.<sup>7</sup>

Last year, FDA announced a new comprehensive plan for tobacco and nicotine regulation aimed at better protecting children and significantly reducing tobacco-related disease and death. A component of that plan involved extending the compliance dates for submission of premarket applications for certain deemed products. That decision also resulted from a careful balancing of public health considerations, with the goals of establishing the proper scientific and regulatory foundation to efficiently and effectively implement the TCA and striking an appropriate balance between regulation and encouraging development of innovative tobacco products that may be less dangerous than cigarettes.

This careful balancing is being challenged by new information, from a variety of sources, about the epidemic rate of increase in youth use of ENDS products, including concerns about flavored e-cigarettes. Consequently, FDA is evaluating our regulatory tools to address this disturbing and accelerating trend. During the summer of 2018, FDA conducted an enforcement blitz of retailers nationwide, which resulted in more than 1,100 Warning Letters and approximately 130 civil monetary penalties being issued to retailers for underage sale of e-cigarettes. Those cases included the illegal sale of Vuse products to minors. This is unacceptable, both legally and as a matter of public health.

To fulfill our public health mandate to address youth addiction to nicotine, FDA is reconsidering its compliance policy for submission of PMTAs for your product and other similar products that were illegally sold by retailers during this blitz, including whether earlier enforcement of the premarket review provision might be warranted. The legal standard for FDA premarket review of a new tobacco product under the PMTA provision includes consideration of whether marketing of the product would be appropriate for the protection of the public health. As part of our regulatory decision-making, FDA will consider evidence that e-cigarettes, such as Vuse, contribute to youth use of and addiction to nicotine. Youth are especially vulnerable to the addictive effects of nicotine because their brains are still developing. Because most tobacco use is established during adolescence, actions to prevent youth from the potential lifetime of nicotine addiction are critical.

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<sup>4</sup> 21 C.F.R. Part 1140 (2018).

<sup>5</sup> TCA § 2(31), (1), Pub. L. 111-31 (June 22, 2009).

<sup>6</sup> 81 Fed. Reg. at 28974.

<sup>7</sup> *Id.* at 28977.

Moreover, FDA regulations state that manufacturers are responsible for ensuring that their covered tobacco products comply with all applicable requirements under 21 C.F.R. part 1140.<sup>8</sup> Given the disturbing trend of ENDS use by minors, it is crucial that tobacco product manufacturers take steps to address youth use of their products.

### **Requested Actions**

FDA requests that you take prompt action to address the rate of youth use of Vuse products.

FDA would like to discuss with you the steps you intend to take to address youth use of your product. Given the importance of this issue, we request an acknowledgement of receipt of this letter within 15 days and a proposed timeline for meeting with FDA.

FDA also requests that, within 60 days of receipt of this letter, you provide a written response to this letter that includes a detailed plan, including specific timeframes, to address and mitigate widespread use by minors. For instance, this plan may include:

- Discontinuing sales to retail establishments that have been subject to an FDA civil monetary penalty for sale of tobacco products to minors within the prior 12 months;
- Developing or strengthening any internal program you have to check on retailers, and reporting to FDA the name and address of retailers that have sold products to minors;
- Eliminating online sales, whether through Internet storefronts controlled by your company or other retailers, or providing evidence to demonstrate that your company's online sales practices do not contribute to youth use of Vuse products;
- Revising your current marketing practices to help prevent use by minors;
- Removing flavored products from the market until those products can be reviewed by FDA as part of a PMTA.

These are examples of actions that you may take to demonstrate that FDA should continue to defer enforcement of the premarket review provisions with respect to Vuse products. You are encouraged to provide additional youth use prevention tools for FDA's consideration.

The youth tobacco use prevention imperative could affect the marketing of products that may have potential public health benefit for a different population, namely, cigarette smokers who may be seeking alternative forms of nicotine delivery. We recognize the challenge here. But steps must be taken to protect the nation's young people.

Failure to respond to this letter may result in FDA taking action to enforce the premarket authorities in the TCA with respect to Vuse products. Products that are required to have premarket authorization but do not have such authorization are adulterated within the meaning of section 902(a)(6) of the FD&C Act.

FDA will review the information provided by your firm. If the agency determines that it should enforce the premarket authorization requirements in the TCA with respect to Vuse products, we intend to communicate our expectations to you.

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<sup>8</sup> See 21 C.F.R § 1140.10.

The requested information should be submitted to:

Imelda Paredes  
Senior Regulatory Counsel  
Center for Tobacco Products, Office of Compliance and Enforcement  
[Imelda.Paredes@fda.hhs.gov](mailto:Imelda.Paredes@fda.hhs.gov)

General information relating to PMTA requirements can be found on our web site at  
<https://www.fda.gov/TobaccoProducts>.

Sincerely,

/Scott Gottlieb/

Scott Gottlieb, M.D.  
Commissioner of Food and Drugs