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The Food and Drug Administration’s (FDA’s) recently published draft guidance, Modifications to Compliance Policy for Certain Deemed Tobacco Products (hereinafter, the “Revised Compliance Policy Draft Guidance”)[1], revises the Agency’s controversial “compliance policy” for new deemed tobacco products on the market when the Deeming Rule went into effect on August 8, 2016. We describe FDA’s proposed changes to the policy below and what companies can do to remain in compliance.

Compliance Policy Background: The Deeming Rule

On August 8, 2016, the Deeming Rule went into effect, extending FDA’s tobacco product authority to previously unregulated categories such as Electronic Nicotine Delivery Systems (ENDS, including e-liquids and vapor devices), cigars, hookah and pipe tobacco. Now, these deemed tobacco products and their components and parts are subject to the Tobacco Control Act, including the requirement that all “new” products first marketed or modified after the February 15, 2007 grandfather date obtain FDA premarket authorization.

Rather than force all new deemed tobacco products off the market when it went into effect, the preamble to the Deeming Rule created a “compliance policy” whereby non-grandfathered deemed tobacco products on the market on August 8, 2016 are permitted to remain on the market without FDA authorization, so long as complete premarket applications are submitted by established compliance dates. The initial compliance policy in the rule required Substantial Equivalence (SE) Reports[2] be filed by February 8, 2018, and Premarket Tobacco Product Applications (PMTAs) by August 8, 2018. New products intended to enter the market after August 8, 2016 cannot take advantage of the compliance policy, and must obtain FDA marketing authorization before entering the U.S. market.

FDA’s First Compliance Policy Modification as Part of Comprehensive Plan

On July 28, 2017, in one of his first major actions as FDA Commissioner, Dr. Scott Gottlieb announced a new “comprehensive regulatory plan to shift the trajectory of tobacco-related disease, and death” that, among other things, delayed the Deeming Rule’s premarket authorization compliance policy deadlines. More specifically, FDA modified the compliance dates based on the type of tobacco product (i.e., combustible vs. non-combustible), rather than the type of application (i.e., SE Report vs. PMTA). Under the new timelines, premarket applications for (1) deemed combustibles such as cigars and hookah tobacco were due by August 8, 2021, and (2) deemed non-combustibles such as ENDS were due by August 8, 2022. FDA also eliminated the 12-month sunset period in the original compliance policy,[3] noting in its guidance that products could remain on the market pending review of timely-submitted applications (so long as those applications were complete and accepted by FDA for scientific review).
The Revised Compliance Policy Draft Guidance: FDA's Modified Compliance Policy and Enforcement Priorities

combustible products.”

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where there is a greater threat to public health”; and (ii) “to balance that public health threat against the potential

prompt filing of premarket submissions for certain ENDS products”; (ii) “to focus the Agency’s enforcement resources

With that in mind, FDA’s stated goals for the Revised Compliance Policy Draft Guidance are: (i) “to encourage more

users in 2018[,]” which amounts to a increase of 1.5 million minors since the previous year.

In November 2018, Commissioner Gottlieb then announced that FDA would focus its youth prevention efforts on the

availability of flavored products. Specifically, FDA would use its ability to modify the compliance policy in order to

limit the availability of flavored ENDS (other than tobacco, mint, menthol and unflavored products) to adult-only brick- 

and-mortar retailers, and online stores with heightened age-verification procedures. In other words, the Agency warned

that flavored ENDS not sold in this manner would be subject to a revised PMTA compliance deadline, to be determined.

New Draft Guidance Modifying the Compliance Policy

It was not until March 13, 2019 that FDA published the Revised Compliance Policy Draft Guidance, making formal its

November 2018 proposal to modify the compliance policy, along with some critical adjustments. The draft guidance makes clear that the purpose of the revised policy for flavored ENDS (and cigars) is to combat the “public health threat” posed by the documented “significant increase in youth use of ENDS products.”[4] Indeed, Commissioner Gottlieb’s statement accompanying the draft guidance noted, among other things, that “the most recent data show more than 3.6 million middle and high school students across the country were current ([i.e.,] past 30 day) e-cigarette users in 2018[,]” which amounts to a increase of 1.5 million minors since the previous year.[5]

With that in mind, FDA’s stated goals for the Revised Compliance Policy Draft Guidance are: (i) “to encourage more prompt filing of premarket submissions for certain ENDS products”; (ii) “to focus the Agency's enforcement resources where there is a greater threat to public health”; and (ii) “to balance that public health threat against the potential benefit to providing adult smokers noncombustible options to allow them to completely switch from the use of combustible products.”[6]

FDA’s Modified Compliance Policy and Enforcement Priorities

The Revised Compliance Policy Draft Guidance:

1. Eliminates the compliance policy altogether for flavored ENDS (other than tobacco, mint, menthol and unflavored products) sold or marketed in a manner that FDA believes is (a) targeted to minors or likely to promote ENDS use by minors, or (b) offered for sale in ways that pose a greater risk of minor access. As we discuss in more detail below, such products will be subject to immediate enforcement, and may be forced off the market until the manufacturer can apply for, and obtain, FDA marketing authorization.

2. Shortens the compliance policy by one year for all flavored ENDS (other than tobacco, mint, menthol and unflavored products), even if such products are marketed responsibly to adults. Such flavored products on the market on August 8, 2016 now have until August 8, 2021 to submit PMTAs (which must be accepted by FDA for substantive review), except that if such products are targeted to minors or sold in a manner that poses a greater risk to minors, as noted above, they will be subject to immediate enforcement. After August 8, 2021, FDA’s decision to prioritize enforcement against products without marketing authorization will be determined on a case-by-case basis.

3. Keeps in place the existing compliance policy for tobacco, mint, menthol and unflavored ENDS on the market as of August 8, 2016. Accordingly, these products still have until August 8, 2022 to submit premarket applications. However, the draft guidance states that FDA may consider revising the compliance policy for these products in the future if the data necessitates such an approach.

4. Eliminates the compliance policy altogether for deemed flavored cigars. This means that any flavored cigars (except for tobacco flavor) that are not grandfathered will also be subject to immediate enforcement. For the time being, flavored cigars that were demonstrably on the market as of February 15, 2007 may continue to be sold (FDA has separately indicated it is considering promulgating a rule to ban the sale of flavored cigars that are grandfathered).

5. Keeps in place the existing compliance policy for other deemed tobacco products. Specifically, the premarket
application compliance dates remain August 8, 2021 for waterpipe and dissolvable tobacco, which are non-combustible, and August 8, 2022 for pipe tobacco, which is combustible.

As described above, the draft guidance indicates that the Agency plans to prioritize enforcement of flavored ENDS (other than tobacco, mint, menthol and unflavored products) that are (1) “targeted to minors or likely to promote use of ENDS by minors,” and (2) offered for sale in ways that pose a greater risk of minor access.

**Targeting or Promoting the Use of ENDS to Minors**

While the draft guidance does not specify what actions FDA would consider targeting or promoting the use of ENDS to minors in this context, it does indicate that the Agency is evaluating how companies may utilize social media to market to minors, as well as radio and television (which are platforms that are prohibited for cigarette advertising). FDA further implied that products with labeling and/or advertising that use “youth appealing cartoons as well as the use of minors or people who appear to be minors in multimedia advertisements” could be the subject of enforcement. This seems to indicate that the Agency may cast a wider net beyond, for example, the e-liquid products that have previously been targeted for warning letters for imitating specific kid-appealing foods.\(^7\)

**Products Offered for Sale in Ways that Pose a Greater Risk of Minor Access**

FDA further indicated that flavored ENDS (other than tobacco, mint, menthol and unflavored products) offered for sale in ways that pose a “greater risk of minor access” would not be eligible for the August 8, 2021 PMTA compliance date, but subject to immediate enforcement. The draft guidance identifies the following circumstances which create greater risks of minor access:

1. Products sold in locations that minors are able to enter at any time (e.g., the entire establishment or an area within the establishment);
2. Products sold through retail establishments and online retail locations that have sold to minors – as indicated by FDA’s searchable retailer inspection database – after issuance of the final guidance document;
3. Products sold online without a limit on the quantity of product that a customer may purchase within a given period of time; or
4. Products sold online without independent, third-party age-and identity-verification services that compare customer information against third-party data sources, such as public records.\(^8\)

Notably, the draft guidance expressly places the onus on manufacturers to control distribution and sale of their products to retail customers by, among other things, “requiring terms, conditions, or controls in their contracts with downstream distributors (wholesalers, distributors, importers and/or retailers) to prevent youth access.”\(^9\)

**Prioritization of FDA Enforcement Resources for Non-Grandfathered Flavored Cigars**

FDA's Revised Compliance Policy Draft Guidance also changed FDA's compliance policy applicable to flavored cigars. In particular, beginning 30 days after issuance of the final version of the Revised Compliance Policy Draft Guidance, FDA stated that it will prioritize enforcement actions on flavored cigars (other than tobacco-flavored cigars) that were on the market on August 8, 2016, and that meet the definition of a new tobacco product.\(^10\) FDA Commissioner Gottlieb's statement accompanying the draft guidance explains that the Agency expects that some flavored cigar products will no longer be sold as a result of these new policies.\(^11\) FDA justified its new policy by speculating that, in the absence of FDA’s adjustment of enforcement priorities, “minors who use flavored ENDS products might migrate to flavored cigars” after the new FDA compliance policy is finalized, attempting to analogize it to “the migration of users of cigarettes with characterizing flavors to cigars with characterizing flavors” that occurred when the [Family Smoking Prevention and] Tobacco Control Act banned cigarettes with characterizing flavors (except menthol).\(^12\) This concern was only magnified by the FDA’s belief that “minors have a tendency to be polytobacco users and, therefore, may switch to other flavored tobacco products like flavored cigars if flavored ENDS are no longer available.”\(^13\) In seeking to find supporting evidence of this theory, the FDA cited the apparent transition of adult users of clove-flavored cigarettes becoming adult users of clove-flavored cigars after the Tobacco Control Act banned clove-flavored cigarettes.\(^14\)

In addition, FDA explained the rationale behind its enforcement policy regarding new mint-flavored and menthol-flavored cigars (as compared to mint-flavored and menthol-flavored ENDS products). Specifically, the Agency explained that since regular cigar smokers are at increased risk (as compared to nonusers) for many of the same diseases as cigarette smokers, there is no similar potential public health benefit to allowing new mint-flavored and menthol-flavored cigars to remain on the market. That said, there is an important limitation to this new policy. Because the Tobacco Control Act defines the term “new tobacco product” as excluding tobacco products marketed “as of February 15, 2007,” FDA’s new compliance policy does not apply to, and does nothing to limit the sale of, these grandfathered tobacco products (which could include certain flavored cigars).

**Other Deemed Tobacco Products**
FDA indicated in the draft guidance that it also considered revising premarket authorization enforcement priorities for other categories of deemed tobacco products, but chose not to for several reasons, despite concerns of significant youth use in some cases. Specifically, with respect to waterpipe tobacco, FDA noted that “due to remaining questions, including questions related to how such products might be used in the absence of flavors, FDA is not changing its compliance policy at this time.”[15] Among other reasons for the disparate treatment of waterpipe tobacco (as compared to flavored ENDS and cigars), FDA noted that “waterpipe tobacco does not appear to have the same ease of use particularly on school grounds, as ENDS products and cigars, due to the cumbersome nature of the related equipment.”[16] With respect to pipe tobacco and dissolvable tobacco products, FDA noted that these products “do not appear to have wide-spread, significant youth use at this time, so FDA is not currently revisiting the compliance policy with respect to such products.”[17]

Accordingly, it appears that the premarket application compliance dates remain August 8, 2021 for waterpipe and dissolvable tobacco, which are non-combustible, and August 8, 2022 for pipe tobacco, which is combustible.

Misplaced Focus on Flavors in ENDS?

Commissioner Gottlieb’s statement detailed that FDA expects that the result of the forthcoming policy changes will be that: (i) some flavored ENDS will no longer be sold at all; and (ii) that other flavored ENDS that continue to be sold will be sold only in a manner that prevents youth access, while premarket authorization for these products is sought from the FDA by 2021.[18] While there is no doubt that past-30 day use by minors increased in 2018, vapor advocates and trade groups have questioned FDA’s focus on flavors as the primary cause of the surge. In a letter sent to FDA last month, the Smoke-Free Alternatives Trade Association (SFATA) concluded:

Flavored vapor products are an important tobacco harm reduction tool for adult smokers, who typically prefer a variety of fruit, dessert and other vapor product flavors. Accordingly...we believe the Agency's efforts to restrict access to all flavored vapor products, as well as threats to eliminate the August 8, 2022 Premarket Tobacco Product Application (PMTA) compliance policy deadline for products on the market, is misplaced – and will ultimately harm the public health. Attempting to solve the problem of youth use by focusing on flavors, rather than examining other potential causes of the recent surge, risks losing out on all the upside of vaping technology. Rather, a broader approach considering all of the likely causes of increased youth initiation (e.g., high nicotine salt concentrations, social media, retailer access, straw purchases, etc.), as well as enforcement of existing age-restrictions and FDA requirements, would better protect vulnerable youth without eliminating a major “off ramp” for adult smokers.

Takeaways for the ENDS Industry: Staying in Compliance

Regardless, in order to avoid potentially being subject to immediate enforcement, and to remain eligible for the August 8, 2021 PMTA compliance date, manufacturers of flavored ENDS must work with their retailers and distributors to ensure that their products are not sold in (1) all-age retailers (i.e., non-adult only facilities such as convenience stores and gas stations) that do not have separate walled-off section for flavored products, (2) online stores that do not have a limit on bulk purchases or third-party age and identity verification services, or (3) brick-and-mortar and online stores that have previously been cited for selling products to minors. Restricting the availability of flavored ENDS in this manner will effectively prohibit certain types of retailers (e.g., convenience stores and gas stations) from selling these products. While this appears to contravene Section 906(d)(1) of the Tobacco Control Act which prohibits FDA from restricting “the sale of any tobacco products in face-to-face transactions by a specific category of retail outlets,” it remains to be seen whether this will be challenged in court.

Manufacturers must further ensure that their products are not viewed as targeting or promoting use to minors. While it is unclear exactly what this means, we recommend companies review their labeling, packaging, social media, websites, and advertising/marketing materials with the understanding that FDA could broadly argue that the use of certain flavors, descriptive flavor names, packaging and label colors, images of food, fruit, or desert, cartoon images or illustrations, playful characters, or young models, among other things, might trigger immediate enforcement under the modified compliance policy.

Finally, even if you can avoid immediate enforcement for your flavored ENDS products, the August 8, 2021 compliance date is fast approaching. It is critical that companies start working to prepare PMTAs sooner rather than later to have any chance of meeting that deadline.

FDA is accepting comments on the Revised Compliance Policy Draft Guidance until April 15, 2019. The modified compliance policy will become effective 30 days after the final guidance is published.


[2] Only tobacco product categories with “grandfathered” predicate products on the market as of February 15, 2007 (e.g., cigars, hookah) are eligible for the SE pathway. As there are no known grandfathered ENDS products, all ENDS must go through the PMTA process. For more on SE Reports see: https://www.fda.gov/tobaccoproducts/labeling/tobaccoproductreviewevaluation/substaintialequivalence/default.htm
[3] See 81 Fed. Reg. 28978 (May 10, 2016) ("For newly deemed tobacco products using the PMTA pathway, this continued compliance period will close 36 months after the effective (i.e., 12 months after the 24-month compliance period closes for submission and receipt of PMTAs).


[6] See Ahmed Jamal, et al., Tobacco Use Among Middle and High School Students – United States, 2011-2016, MORBIDITY AND MORTALITY WEEKLY REPORT (MMWR) (2017), Figure 1, available at: https://www.cdc.gov/mmwr/volumes/66/wr/mm6623a1.htm#F1_down.

[7] In those warning letters to over a dozen e-liquid manufacturers, FDA and in some cases the Federal Trade Commission (FTC), alleged that certain e-liquids were misbranded under Section 903(a)(1) of Tobacco Control Act and/or deceptive and misleading under FTC Act Section 5(a). Those warning letters alleged that the labeling and/or advertising of the identified products (i.e., color schemes, label images, brand names, etc.) inappropriately imitated specific food products that are generally marketed toward and/or are appealing to minors, including cereals (e.g., Cinnamon Toast Crunch, Lucky Charms, Fruit Loops, Franken Berry), candies and snacks (e.g., Life Saver, Sour Patch Kids, Gummy Worms, War Heads, Pocky Sticks, Goobers, Tree Top Apple Juice), and desserts (e.g., Unicorn Cakes, Nilla Wafers, Reddi Wip). See U.S. Food and Drug Admin., FDA Newsroom, E-Liquids Misleadingly Labeled or Advertised as Food Products, available at: https://www.fda.gov/tobaccoproducts/newsevents/ucm605729.htm.


[10] Id., at 15.


[13] Id.

[14] Id., at 17.


[16] Id.

[17] Id.


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