CITMA
COALITION OF INDEPENDENT TOBACCO MANUFACTURERS OF AMERICA

April 30, 2019

Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

RE: Draft Guidance, Modifications to Compliance Policy for Certain Deemed Tobacco Products (Docket No. FDA-2019-D-0661)

The Coalition of Independent Tobacco Manufacturers of America (CITMA) respectfully submits these comments in response to the U.S. Food and Drug Administration's (FDA's) recent proposed modifications to its compliance policy related to the marketing of "new deemed products," entitled "Modifications to Compliance Policy for Certain Deemed Products" (Draft Guidance). CITMA respectfully submits that the Draft Guidance, as applied to both cigars and electronic nicotine delivery system (ENDS) products, is procedurally and substantively flawed and should be withdrawn.

CITMA is a trade coalition group that represents small tobacco product manufacturers (STPMs),[1] including manufacturers of finished cigar and ENDS products, their suppliers, and importers of their products. CITMA provides information and advisory support to its member companies to help them understand the impacts of, and comply with, FDA regulations applicable to the manufacture and distribution of tobacco products. CITMA also represents the interests of its members through advocacy before FDA.

On May 10, 2016, FDA issued a final rule deeming all products that meet the statutory definition of a tobacco product, except accessories of newly deemed tobacco products, to be subject to FDA's tobacco product authority (Deeming Rule). In conjunction with the Deeming Rule, FDA announced a compliance policy for newly deemed products that qualify as "new tobacco products" (i.e., products not commercially marketed in the United States as of February 15, 2007, or modified in any physical respect since) but that were on the U.S. market on the August 8, 2016, effective date of the Deeming Rule (CP Products). The initial policy allowed the continued marketing of CP Products until staggered deadlines for filing of premarket review submissions for them (and for up to one year thereafter during FDA's review of such submissions) as follows:

[1] A "small tobacco product manufacturer" is defined as one that "employs fewer than 350 employees." 21 U.S.C. § 387(16).

A. FDA Seeks to Use Selective Enforcement Discretion with Respect to One Requirement (Premarket Authorization) to Circumvent Rulemaking Obligations and Statutory Prohibitions with Respect to Unrelated Policy Goals

The statute is clear that if a product was not on the market "as of February 15, 2007," it is a "new tobacco product" that must be covered by a premarket authorization. Thus, as of the effective date of the Deeming Rule, August 8, 2016, any deemed "new tobacco product" not covered by such an authorization does not comply with the law. However, as explained above, since the issuance of the Deeming Rule, FDA has consistently acknowledged through its enforcement discretion policies the need to defer the filing of premarket submissions for deemed "new tobacco products" on the market on August 8, 2016, and to allow the continued marketing of such products, until FDA has had an opportunity to delineate the requirements for such submissions and industry has had an opportunity to satisfy those requirements. This approach has proven critical to the ENDS industry because all (or virtually all) ENDS products on the market on August 8, 2016, qualify as "new tobacco products" given the nascent status of the segment in the United States on February 15, 2007, and the significant technological advances that have occurred since.

In the Draft Guidance, however, FDA has now proposed that, beginning 30 days after the issuance of the final version of the guidance, FDA would prioritize enforcement regarding the lack of marketing authorization against:

- Flavored ENDS CP Products (other than tobacco-flavored, mint-flavored, and menthol-flavored ENDS products) (Specified Flavored ENDS Products) that are offered for sale in ways that pose a greater risk for minors to access such products. For example:
    - Specified Flavored ENDS Products sold in locations that minors are able to enter at any time (e.g., the entire establishment or an area within the establishment);
    - Specified Flavored ENDS Products sold through retail establishments and online retail locations that have sold to minors after issuance of the final guidance (information about sales to minors identified by FDA is publicly available on FDA's searchable retailer inspection database);
    - Specified Flavored ENDS Products sold online with no limit on the quantity that a customer may purchase within a given period of time; or
    - Specified Flavored ENDS 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.
- Specified Flavored ENDS Products that are offered for sale in the United States after August 8, 2021, without the manufacturer submitting (and FDA receiving) a premarket application; and
- All ENDS CP Products that are targeted to minors or likely to promote use of ENDS by minors. FDA seems to provide the following examples:
    - Use of social media to market products to minors;
    - Use of youth-appealing cartoons, minors, or people who appear to be minors in advertising; and
    - Products that resemble kid-friendly foods and drinks or resemble other non-ENDS products that are often consumed by youth.

quantity limits, as well as restrictions on online promotion, such as use of social media. Indeed, Section 906(d)(4)(A) explicitly required FDA to: (1) promulgate regulations regarding "the sale and distribution of tobacco products that occur through means other than a direct, face-to-face exchange between a retailer and a consumer in order to prevent the sale and distribution of tobacco products to individuals who have not attained the minimum age established by applicable law for the purchase of such products, including age verification"[7] within 18 months of the Family Smoking Prevention and Tobacco Control Act's (TCA's) enactment; and (2) promulgate regulations to "address the promotion and marketing of tobacco products that are sold or distributed through means other than a direct, face-to-face exchange between a retailer and a consumer in order to protect individuals who have not attained the minimum age established by applicable law for the purchase of such products" within 2 years of the TCA's enactment.[8] Moreover, the statute requires rulemaking for any "restrictions on the sale and distribution of a tobacco products, including restrictions on the access to, and the advertising and promotion of, the tobacco product."[9]

On September 9, 2011, FDA published an ANPRM to obtain information related to the regulation of non-face-to-face sale and distribution of tobacco products and the advertising, promotion, and marketing of tobacco products. In particular, FDA requested comments, data, research, and other information related to non-face-to-face sale and distribution of tobacco products and the advertising, promotion, and marketing of such products, including internet advertising and promotion. The comment period closed on January 19, 2012, and there were 310 comments filed to the docket. Since that time, FDA has taken no further steps to promulgate the required regulations to address non-face-to-face sales and the promotion and marketing of tobacco products sold in non-face-to-face transactions.

FDA now attempts to regulate non-face-to-face sales of ENDS products and the marketing and promotion of ENDS products so sold through the modification to its compliance policy. As with a flavor ban, FDA cannot sidestep its mandatory rulemaking obligations on these subjects through the threat of selective enforcement of other unrelated statutory requirements.

2. FDA Cannot Use the Threat of Selective Enforcement of the Premarket Authorization Requirements for Specified Flavored ENDS Products to Sidestep Statutory Prohibitions or Mandates

Section 906(d)(3)(A)(i) of the Act clearly states that FDA may not "prohibit the sale of any tobacco product in face-to-face transactions by specific category of retail outlets."[10] Yet that is exactly what FDA has proposed to do under the Draft Guidance.

The Draft Guidance threatens selective enforcement of the premarket authorization requirements if Specified Flavored ENDS Products are sold in a location that minors are able to enter at any

[7] 21 U.S.C. § 387f(d)(4)(A)(i).
[8] 21 U.S.C. § 387f(d)(4)(A)(ii).
[9] 21 U.S.C. § 387f(d)(1). With respect to advertising and promotion restrictions, in addition to a determination that they are appropriate for the protection of public health, such restrictions must be consistent with the First Amendment. *Id.*
[10] 21 U.S.C. § 387f(d)(3)(A)(i).

their wholesaler customers resell purchased products), application of the policy as written could conceivably result in enforcement action against a Specified Flavored ENDS Product based on its sale in an individual retail outlet that has previously committed an isolated sale to minors violation involving an entirely different product, such as a pack of cigarettes. In addition to "punishing" an innocent party, this would blatantly circumvent the procedural protections mandated in the Act and impermissibly shift FDA's enforcement responsibilities to manufacturers of Specified Flavored ENDS Products.

B. The Draft Guidance's ENDS Policies Are Arbitrary and Capricious Because They Would Result in Absurd Unintended Consequences, Are Not Supported by a Rational Explanation, Particularly in Light of Industry's Reliance on FDA's Previous Compliance Policy, and Would Indiscriminately Pick Winners and Losers

1. The Draft Guidance Would Result in Absurd Unintended Consequences

The effect of the Draft Guidance is that a Specified Flavored ENDS Product could lose its marketing status under FDA's compliance policy based on a completely unrelated action by an unrelated party that has nothing to do with the product at issue. As explained above, for example, if a Specified Flavored ENDS Product winds up in a retail location that has committed one sale to minors violation involving an entirely different product, perhaps a cigarette product, without the marketer of the Specified Flavored ENDS Product even knowing that the product was distributed to that retailer, the Specified Flavored ENDS Product at issue could lose its marketing status.

Once an ENDS product leaves a manufacturer's possession, in most cases the manufacturer no longer has any direct control over its movement in the distribution chain. A product typically passes through one or more wholesalers and distributors before it arrives at a particular retail outlet. Contrary to FDA's assertion in the Draft Guidance that it is "FDA's understanding that manufacturers have the means to control the distribution and sale of their products to retail customers by, for example, including or requiring terms, conditions, or controls in their contracts with downstream distributors (wholesalers, distributors, importers and/or retailers)," manufacturers – particularly small manufacturers like CITMA's members – rarely have direct contractual privity with a consumer-facing retailer or the bargaining power to dictate particular terms of distribution. FDA cannot impose a duty to create contractual privity between a manufacturer and downstream wholesalers, distributors, importers and retailers. Even if a manufacturer were to constantly monitor FDA's retailer inspection database and determine which individual retail outlets have been cited one or more times for a sale to minors violation, that manufacturer would have no way to then control the distribution of its products to avoid those individual outlets. To punish that manufacturer based on circumstances beyond its control would be irrational.

The absurd consequences of this enforcement approach also cause the Draft Guidance to be arbitrary and capricious. It appears that FDA entirely failed to consider these presumably unintended consequences when formulating the Draft Guidance. Where an agency's decision "entirely failed to consider an important aspect of the problem," that decision must be set aside.[17]

[17] *Motor Vehicle Mfr. Ass'n of U.S., Inc. v. State Farm Mut. Auto Ins., Co.*, 463 U.S. 29, 43 (1983).

> This recent increase in e-cigarette use among youths is consistent with observed increases in sales of the e-cigarette JUUL (*8*), a USB-shaped e-cigarette device with a high nicotine content that can be used discreetly and is available in flavors that can appeal to youths. … Sales of JUUL increased by approximately 600% during 2016–2017 (*8*) and increased even further through 2018 (*10*). By December 2017, JUUL held the largest market share of any e-cigarette (*8*). Thus, given that NYTS is fielded annually in the spring, the 2018 data are the first to reflect the impact of rising sales of JUUL and other USB-shaped devices on e-cigarette and overall tobacco product use among U.S. youths.[23]

Until a few months ago, the most popular JUUL flavor was mango. Since JUUL voluntarily removed all "flavors" from the retail market, CITMA understands that mint now represents a significant majority of total JUUL pod sales with little, if any, decrease in total sales. This indicates that sales of JUUL, by far the highest selling ENDS product among both minors and adults, are not driven by specified flavors, undermining FDA's stated rationale for the change in its compliance policy.

Furthermore, the 2017 NYTS data indicate that 72.3% of surveyed minors who used ENDS products reported obtaining them from so-called "social sources," such as friends, family, classmates, or others. By contrast, convenience stores and gas stations served as sources for only 7.7% of all respondents, while vape shops accounted for 12.4%. The 2016 NYTS data are similar, showing that 75% of youth reported obtaining ENDS products from friends, family or other persons, 10.6% from convenience stores and gas stations, and 16.4% from vape shops.

Similarly, in the Draft Guidance, FDA cites the following data:

- According to data from the 2018 NYTS, 14.8 percent of U.S. middle and high school e-cigarette users under 18 years of age reported obtaining e-cigarettes in the past 30 days from a vape shop or other store that sells e-cigarettes and 8.4 percent reported obtaining them from a gas station or convenience store.
- Evidence from Wave 4 of the PATH Study revealed that 7.2 percent of youth past 30-day ENDS product users reported that they usually get their ENDS products from the Internet.
- A recent survey of adolescents found that 32.2 percent of them purchased the vaping device online.
- The 2018 NYTS data revealed that 6.5 percent of U.S. middle and high school e-cigarette users under age 18 reported obtaining their e-cigarettes in the past 30-days on the Internet.

Thus, neither the historical data nor the data specifically cited by FDA in the Draft Guidance indicate that non-age-gated retail locations, such as convenience stores, gas stations and drug stores, are a significant source of youth-obtained ENDS products.

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[23] Gentzke AS, Creamer M, Cullen KA, et al. Vital Signs: Tobacco Product Use Among Middle and High School Students — United States, 2011–2018. MMWR Morb Mortal Wkly Rep 2019;68:157–164. DOI: http://dx.doi.org/10.15585/mmwr.mm6806e1.

post a sign at the door that states that entry is restricted to age 18 or older? Would parents be permitted to enter the store with their children? These ambiguities only reinforce the arbitrary and capricious nature of the Draft Guidance.

III. The Draft Guidance's Policies on Specified Flavored ENDS Products Violate the First Amendment

The Draft Guidance states that FDA will prioritize enforcement of products that "are targeted to minors or likely to promote use of ENDS by minors." In this section of the Draft Guidance, FDA references: (a) advertising through television, radio, and other media; (b) use of social media to market tobacco products to minors; (c) labeling and advertising of ENDS products including "youth-appealing cartoons" and "people who appear to be minors;" and (d) "products that resemble kid-friendly foods and drinks or resemble other non-ENDS products that are often consumed by youth." FDA does not, however, provide a sufficient explanation of what kinds of communication would actually trigger FDA enforcement under the modified compliance policy.

For example, does this section mean that FDA will enforce against any Specified Flavored ENDS Products advertised on television, radio, or other (any?) media, regardless of the communication's content or audience? If so, the policy would represent an impermissibly overbroad commercial speech restriction.[26] How will FDA, and how should industry, determine what qualifies as a "youth-appealing cartoon?" Would any non-photographic representation of a person or animal trigger enforcement? Such an approach, and the absence of any meaningful criteria for understanding the scope of FDA's enforcement policy, would likewise raise significant First Amendment concerns.

Further, if FDA determines that an individual retailer engaged in communication about a product that is "targeted to minors or likely to promote use of ENDS by minors," could the manufacturer of the product lose the ability to continue marketing that product under the compliance policy in other locations based on independent action by one isolated retailer? These ambiguities would impermissibly chill protected commercial speech and, again, could result in devastating economic consequences for manufacturers based on conduct wholly outside of their control.

IV. The Drastically-Shortened Deadline for PMTAs for CP ENDS Products Upends Industry's Serious Reliance Interests Based on Consistent FDA Statements Without an Adequate Basis for Doing So

As noted above, industry relied on FDA's August 2017 Compliance Policy that reset the filing deadline for ENDS CP Product PMTAs as August 8, 2022. In announcing the August 2017 Compliance Policy, FDA stated that the extension will "provide manufacturers additional time to

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[26] Under the test articulated in *Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n*, 447 U.S. 557, 561 (1980), a content-based restriction on commercial speech is subject to intermediate scrutiny. If commercial speech concerns lawful activity and is not misleading, "the asserted governmental interest" in restricting it must be "substantial." 447 U.S. at 566. Courts then assess "whether the regulation directly advances the governmental interest asserted [to a material degree], and whether it is not more extensive than necessary to serve that interest." *Id.*; *see also Edenfield v. Fane*, 507 U.S. 761, 767 (1993).

regulations governing what information those applications must include and what product standards they must meet."

- "Manufacturers, in turn, will need time to prepare higher-quality applications with the benefit of that forthcoming guidance."

Despite these repeated commitments to issue a final PMTA guidance document for ENDS products, regulations outlining what information the agency expects to be included in PMTAs, and products standards, as well as guidance for the testing of harmful and potential harmful constituents (HPHCs), which is critical for the submission of PMTAs, FDA has provided none of these foundational rules or guidance.

Nevertheless, on March 19, 2019, Former Commissioner Scott Gottlieb stated that there is already guidance available on the PMTA process (apparently referencing the highly ambiguous Draft Guidance issued on May 10, 2016,[32] on which FDA received significant feedback via stakeholder comments and which FDA has for almost 3 years committed to finalize) and that he "[doesn't] know what [ENDS manufacturers] are waiting for" and "[doesn't] know why they're not further along on the PMTA process."[33] He further stated that "the onus is obviously on the e-cigarette manufacturers to file…if they had gotten under way a couple years ago, they'd probably be pretty close to the finish line right now."[34]

The answers to Dr. Gottlieb's inquiries are clear. Why would companies – particularly small manufacturers like CITMA's members – complete the expensive and time-consuming work to prepare a PMTA before the repeatedly promised guidance and foundational rules are issued? If a company developed the data it thought would be adequate to support PMTA approval, and FDA subsequently published final guidance or regulations that went a different direction, the company would be irreparably harmed by having to start anew. Likewise, if FDA subsequently provided a more streamlined approach than that adopted by the company in guessing what would be sufficient to FDA, the company would be at a potentially devastating competitive disadvantage.

Further, if a company filed a PMTA before August 8, 2022, without the benefit of such final guidance or regulations, the Agency might take the position that the August 2017 Compliance Policy ceased to apply to the ENDS CP Product upon the company's withdrawal of the earlier-filed PMTA or negative action on the PMTA taken by FDA. This could result in the company's having to remove the subject ENDS CP Product from the market earlier than the company otherwise would have had to (if at all) had the company filed by the August 8, 2022, compliance date and received the full benefit of the promised guidance and regulations. Faced with these potential consequences, and relying on the Agency's August 2017 Compliance Policy, its stated rationale for issuing it, and FDA's legal defenses thereof, small manufacturers have acted in an eminently reasonable manner and in good faith.

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[32] Draft Guidance for Industry, Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems (May 2016).

[33] A conversation with departing FDA Commissioner Scott Gottlieb on his tenure and policy reforms, Hutchins Center on Fiscal & Monetary Policy and the USC-Brookings Schaeffer Initiative for Health Policy at Brookings (March 19, 2019), *available at* https://www.youtube.com/watch?v=fAzdgASEZB8&feature=youtu.be.

[34] *Id.*

VI. With Respect to Cigar CP Products, FDA's Draft Guidance is Both Inconsistent with Statutory Mandates and Arbitrary and Capricious

The Draft Guidance would essentially revoke FDA's compliance policy as applied to certain cigar CP Products. Specifically, the Draft Guidance states, "At this time, in addition to modifying the compliance policy for ENDS products, FDA is also modifying the August 2017 Compliance Policy for flavored cigars. Beginning 30 days after issuance of a final guidance, FDA will prioritize enforcement of actions with respect to flavored cigars (other than tobacco flavored) that were on the market on August 8, 2016, and that meet the definition of a new tobacco product." Draft Guidance at 15. In other words, FDA would break from its previous compliance policy by enforcing the premarket review requirements against "flavored cigars (other than tobacco flavored)" that otherwise qualified as CP Products (Specified Flavored Cigars). Under the August 2017 Compliance Policy, Specified Flavored Cigars may remain on the market until at least August 8, 2021, and, if the marketer files a marketing application for a product by that date, thereafter pending FDA review of the timely filed application.

The Draft Guidance's proposed policy changes for Specified Flavored Cigars would violate the FFDCA in multiple ways and is arbitrary and capricious under the APA. Although the Draft Guidance generally suffers from vagueness, it appears that FDA contemplates using selective enforcement discretion with respect to one statutory requirement – premarket authorization for "new tobacco products" – to accomplish policy objectives that explicitly require notice-and-comment rulemaking (i.e., flavor restrictions for cigars). This it cannot do.

A. FDA Seeks to Use Selective Enforcement Discretion with Respect to One Requirement (Premarket Authorization) to Circumvent Rulemaking Obligations with Respect to Unrelated Policy Goals

As noted above, the statute categorizes as a "new tobacco product" requiring premarket authorization any product that was not commercially marketed in the United States "as of February 15, 2007" or that has undergone any physical modification since. Thus, as of the August 8, 2016, effective date of the Deeming Rule, any deemed "new tobacco product" not covered by such an authorization does not comply with the law. However, as explained above, since the issuance of the Deeming Rule, FDA has consistently acknowledged through its enforcement discretion policies the need to defer the filing of premarket submissions for deemed "new tobacco products" on the market on August 8, 2016, and to allow the continued marketing of such products, until FDA has had an opportunity to delineate the requirements for such submissions and industry has had an opportunity to satisfy those requirements. This approach has proven critical to the cigar industry, which has seen many new entrants (both companies and products) since February 15, 2007, and which has made changes to products since then, including to comply with other laws (e.g., local laws establishing minimum-package-size requirements for certain cigars).

In the Draft Guidance, however, FDA proposes that, beginning 30 days after the issuance of a final guidance, FDA would prioritize enforcement regarding the lack of a marketing authorization against any Specified Flavored Cigar. In other words, FDA appears to propose that the Agency would only exercise its enforcement discretion to permit the continued marketing of

premise that is flatly contradicted by the agency's own record does not constitute reasoned decisionmaking, and cannot survive review under the arbitrary and capricious standard."[43] This is the case even where an agency is merely modifying a previous enforcement policy. In such a case, although the agency "need not explain why the reasons for the new policy are better than the reasons for the old policy," it "must nevertheless engage in reasoned decisionmaking."[44] The modification to FDA's compliance policy for cigar CP Products embodied in the Draft Guidance lacks support in the Agency's own record and lacks common sense.

In the Draft Guidance, FDA attempts to support the dramatic proposed changes in its compliance policy for Specified Flavored Cigars essentially based on two main suppositions:

- Minors "continue to use" flavored cigars due, in part, to their flavors; and
- Implementation of the flawed modifications to the compliance policy for Specified Flavored ENDS Products could result in minors' migrating from such products to flavored cigar products.

Draft Guidance at 15-18.

First and tellingly, the Agency cites no data suggesting that flavored cigar use by minors is either high or has increased in recent years in a manner that would justify such a draconian response. FDA does not do so because no such data exist. Data from the 2017 NYTS indicate a linear decrease in past-30-day use of all cigars by high school students from 11.6% to 7.7% since 2011. Youth-usage rates of flavored cigar products appear lower still. For example, the PATH data indicate that youth smoke flavored cigars at a rate of 1.8% (based on past-30-day use), and only 35.2% of this tiny percentage reported smoking more than 5 days per month.[45]

FDA seeks to justify its proposal by asserting that "[c]urrent information shows that minors continue to use these dangerous combustible tobacco products due, in part, to the availability and appeal of fruit and other flavors." Draft Guidance at 16. However, the 2019 Dai study that FDA cites for this proposition in no way addresses the reasons for the flavored cigar use in the survey data analyzed, and it certainly does not demonstrate that such use occurs because of the appeal of "fruit and other flavors." The Dai study also shows that the proportion of current youth cigar smokers reporting flavored cigar use in the past 30 days in fact decreased to a statistically significant degree from 2014 to 2016 and decreased again between 2016 and 2017, although not to a statistically significant degree. The Draft Guidance does not acknowledge this encouraging trend or how it informed FDA's proposed policy change.

While the 2019 Dai study cited in the Draft Guidance does not support FDA's assertion that the shrinking percentage of youth who do smoke flavored cigars choose to do so because of the availability of flavored products, the PATH data also would not allow the Agency to reach such a conclusion. For example, the PATH survey failed to ask respondents to prioritize their reasons for smoking cigars, including with questions that would allow researchers to understand the

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[43] *City of Kansas City, Mo.*, 923 F.2d at 194.
[44] *Batalla* Vidal, 279 F. Supp. 3d at 431.
[45] H. Daniel Roth Associates, Inc., Analysis of Flavored Cigar Use by Youth and Young Adults in the Population and Assessment of Tobacco and Health (PATH) Wave 1 Survey, at 9, 10 (July 18, 2018) (Attachment A).

marketing of a combustible tobacco product." *Id.* However, the experience of smoking a cigar differs dramatically from using an ENDS product, making the comparison to substituting a cigar product for a cigarette product inapposite.[47] Even if both products have a similar characterizing flavor, the harshness of even flavored combusted cigar tobacco seems an unlikely substitute for a youth accustomed to inhaling aerosolized, flavored e-liquid from an ENDS device. In addition, the market conditions at issue in the clove cigarette example would not apply under the Draft Guidance, making the comparison less credible still. Unlike the clove cigarettes in the referenced example, Specified Flavored ENDS Products would remain available from social sources and certain retailers, including on the Internet, and tobacco-, mint-, and menthol-flavored ENDS CP Products would remain widely available. This distinction, and the relatively low flavored cigar youth use rates before and after the introduction of ENDS products to the market, further undermine FDA's unsupported assertion that migration concerns justify ceasing to apply its compliance policy to all Specified Flavored Cigars.

VII. Withdrawing FDA's Enforcement Discretion Policy for Specified Flavored Cigars Upends Industry's Serious Reliance Interests Based on Consistent FDA Statements Without an Adequate Basis for Doing So

Industry relied on FDA's August 2017 Compliance Policy that reset the filing deadline for cigar CP Product marketing applications to August 8, 2021. In announcing the August 2017 Compliance Policy, FDA stated that the extension will "provide manufacturers additional time to develop higher quality, more complete applications informed by further guidance from the agency."[48] The Agency further stated that "FDA plans to issue foundational rules to make the product review process more efficient, predictable, and transparent for manufacturers … Among other things, the FDA intends to issue regulations outlining what information the agency expects to be included in . . . reports to demonstrate Substantial Equivalence (SE)."[49]

One year later, on August 2, 2018, FDA likewise stated: "We all need to be on the same page regarding the basic 'rules of the road,' especially when it comes to what's expected in premarket applications ... We will begin publishing these foundational proposed rules in the coming months. They will lay out a transparent, modern, and science-based framework for manufacturing practices and the development of tobacco product applications that meet the legal requirements."[50] Similarly, and as discussed above, FDA has defended the August 2017 Compliance Policy before the United States District Court for the District of Maryland as necessary and reasonable given the absence of foundational rules.

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[47] While the Draft Guidance's example suggests that clove cigars may serve as substitutes for clove cigarettes, differences in cigar and cigarette tobacco actually render their smoking experiences unique and, in general, cigars not substitutable for cigarettes. The tobaccos used in cigars contain far fewer reducing sugars than cigarette tobacco; cigars contain traditional, dark air cured tobaccos, which provide them a distinctly cigar taste and aroma, despite any added flavoring. Cigarettes contain flue-cured and aromatic tobaccos that generally provide a "smoother" smoking experience.

[48] FDA News Release, "FDA announces comprehensive regulatory plan to shift trajectory of tobacco-related disease, death" (July 28, 2017), www.fda.gov/newsevents/newsroom/pressannouncements/ucm568923.htm.

[49] *Id.*

[50] Advancing Tobacco Regulation to Protect Children and Families: Updates and New Initiatives from the FDA on the Anniversary of the Tobacco Control Act and FDA's Comprehensive Plan for Nicotine (Aug. 2, 2018), https://www.fda.gov/news-events/fda-voices-perspectives-fda-experts/advancing-tobacco-regulation-protect-children-and-families-updates-and-new-initiatives-fda.

- On **January 16, 2018**, HHS advised CITMA that it estimated acting on the appeal by April 14, 2018.

- On **April 26, 2018**, HHS informed CITMA that action on the appeal would occur by May 14, 2018.

- On **June 6, 2018**, HHS informed CITMA that the appeal was number 114 in a queue of 129.

- On **July 24, 2018**, HHS informed CITMA that the appeal was just about ready for a response.

- On **August 6, 2018**, HHS informed CITMA that the appeal's decision only needed a final legal review from the Office of the General Counsel and that HHS should issue the decision by the end of the month.

- After repeated emails and calls, HHS indicated on **March 8, 2019**, that it was checking on the status of CITMA's appeal.

- After further repeated follow-up emails and calls, HHS indicated on **April 4, 2019**, that "an appeal response has been prepared and it's in the latter stages of review and clearance." CITMA has not yet received any appeal response.

Lacking promised guidance and regulations as well as actionable responses to its FOIA requests, small manufacturers like CITMA's members have reasonably relied on the August 2017 Compliance Policy and FDA's above-referenced statements in deferring submitting premarket applications for Specified Flavored Cigars. If a company developed the data it thought would be adequate to support a marketing authorization, and FDA subsequently published promised guidance or regulations that went a different direction, the company would be irreparably harmed by having to start anew. Likewise, if FDA subsequently provided a more streamlined approach than that adopted by the company in guessing what would be sufficient to FDA, the company would be at a potentially devastating competitive disadvantage.

Further, if a company filed an SE report or exemption request before August 8, 2021, without the benefit of such guidance or regulations, the Agency might take the position that the August 2017 Compliance Policy ceased to apply to the cigar CP Product upon the company's withdrawal of the earlier-filed submission or negative FDA action on the submission. This could result in the company having to remove the subject cigar CP Product from the market earlier than the company otherwise would have had to (if at all) had the company filed by the August 8, 2021, compliance date and received the full benefit of the promised guidance and regulations. Faced with these potential consequences, and relying on the Agency's August 2017 Compliance Policy, its stated rationale for issuing it, and FDA's legal defenses thereof, small manufacturers have acted in an eminently reasonable manner and in good faith by deferring submitting marketing applications for Specified Flavored Cigars.

Importantly, this subset should not include menthol-flavored cigars. Withdrawing enforcement discretion for menthol cigar CP Products could lead consumers of such products to adopt use of menthol cigarettes, which, while different in meaningful respects (e.g., tobacco blends) and use patterns from menthol-flavored cigars, would remain legal and widely available. This result would run counter to FDA's public health mission. In addition, and consistent with FDA's proposed approach to tobacco-, mint-, and menthol-flavored ENDS CP Products, the Agency's modified policy should not apply to menthol cigar CP Products unless FDA can demonstrate that menthol cigars present meaningful youth-appeal and -use concerns, a point that the Draft Guidance does not appear to assert.

IX. A 30-Day Implementation Period for the Draft Guidance's Modifications to the Compliance Policy for Cigars Is Inappropriate

As explained above, the proposed 30-day implementation period for withdrawing the enforcement discretion policy for any flavored cigar CP Products would not allow industry sufficient time to seek and obtain FDA marketing authorizations to keep within-scope products on the market without interruption. In all likelihood, industry would have to remove such products from the market in order to seek FDA authorization to reintroduce them. This is precisely the result the Agency sought to avoid in even its initial version of the compliance policy announced in May of 2016 and would upend the significant reliance interests of the industry. Again, without any data demonstrating an increase in youth usage of flavored cigar products since 2016, or any credible basis to assert that the Agency's proposed policies for Specified Flavored ENDS Products would lead to one, FDA should simply continue implementing the 2017 Compliance Policy and retain the August 8, 2021, compliance date for submission of marketing applications for cigar CP Products.

However, if the Agency seeks to proceed with finalizing the Draft Guidance's proposal to withdraw the August 2017 Compliance Policy as applied to any flavored cigar CP Products, FDA should provide a reasonable implementation period that reflects the industry's warranted reliance on the 2017 Compliance Policy and the business impacts that such a change would entail. Note that the FFDCA's "special rule" for cigarettes (and their components) with non-menthol and non-tobacco "characterizing flavors" did not take effect for three months after the TCA's enactment (or triple the implementation period proposed in the Draft Guidance).[54] Given that provision's presence in earlier versions of the TCA introduced in Congress, the cigarette industry in effect had several years' worth of advance notice to prepare for the special rule, which conservatively impacted only 1% of cigarettes on the market at the time. Circumstances justify a far longer implementation period for Specified Flavored Cigars, which may represent a relatively large percentage of the current cigar market.

At the outset, due to the complexity of the manufacturing, distribution, and retail system, industry would need substantial time (i.e., more than 30 days) to effectively implement any modification to the compliance policy for Specified Flavored Cigars. This implementation process would involve determining and documenting the status of products thereunder and managing affected products in inventory as well those already in the distribution system on the

[54] 21 U.S.C. § 387g(a)(1)(A).

Sincerely,

Kevin Altman

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