IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

AMERICAN ACADEMY OF PEDIATRICS, *et al.*, Plaintiffs, v. UNITED STATES FOOD AND DRUG ADMINISTRATION, *et al.*, Defendants.	Civil Action No. 8:18-cv-883-PWG

DECLARATION OF MITCHELL ZELLER

I, Mitchell Zeller, declare as follows:

1. I am the Director of the Center for Tobacco Products ("CTP"), United States Food and Drug Administration ("FDA"), a position I have held since March 2013. In this role, I direct the development and implementation of programs and policies for regulating the manufacture, marketing, and distribution of tobacco products. In my capacity as Director of CTP, I am fully familiar with the instant matter and the facts stated herein.

2. I have dedicated my career to working on FDA issues (nearly 37 years), including the last 25 years focused on tobacco regulation. I am a graduate of Dartmouth College and the American University Washington College of Law. I began my career as a public interest attorney in 1982 at the Center for Science in the Public Interest working on FDA food safety and nutrition issues. In 1988, I served as counsel to the Human Resources and Intergovernmental Relations Subcommittee of the House of Representatives Government Operations Committee, where I conducted oversight of enforcement of federal health and safety laws, including human and animal drugs, dietary supplements, and food policies at FDA. In 1993, I joined the staff of

then-FDA Commissioner, Dr. David Kessler, M.D., on a two-week assignment to examine the practices of the tobacco industry. This assignment led to my serving as associate commissioner and director of FDA's first Office of Tobacco Programs where I led FDA's efforts to craft the agency's 1996 tobacco regulations. In this capacity, I represented FDA before Congress, federal and state agencies, and served as an official United States delegate to the World Health Organization Working Group for the Framework Convention on Tobacco Control. In 2000, I left FDA to continue my work in tobacco control as executive vice president of the American Legacy Foundation, where my responsibilities included marketing, communications, strategic partnerships, and creating the foundation's first Office of Policy and Government Relations. I later joined Pinney Associates as senior vice president in 2002, where I remained until I took my current position as Director of CTP. In that role, I provided strategic planning and communications advice on domestic and global health policy issues involving the treatment of tobacco dependence and the regulation of tobacco products and pharmaceuticals.

3. The Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776 (2009) ("TCA") gave FDA authority to "deem" additional tobacco products subject to Chapter IX of the FDCA through notice and comment rulemaking. On May 10, 2016, FDA issued the "deeming rule," which subjected all other tobacco products (except accessories) to the requirements in Chapter IX of the FDCA, including electronic nicotine delivery systems ("ENDS") and cigars. 81 Fed. Reg. 28,974.

4. FDA has used and will continue to use its authority under the TCA and the deeming rule to address serious concerns about tobacco products, including youth use of ENDS and flavored cigars. We are committed to keeping tobacco products out of the hands of youth, and have used our authority and resources forcefully to prevent youth access, curb the marketing

of tobacco products aimed at youth, and educate teens and their families about the health risks of vaping and other tobacco product use. Specifically, since early 2018, these actions have included: (1) in May 2018, issuing 17 warning letters to manufacturers and retailers for selling e-liquids that resembled kid-friendly food products, which prompted all of the recipients to stop selling the violative products;[1] (2) in summer 2018, conducting a nationwide undercover investigation that resulted in over 1,300 warning letters and civil money penalty actions against retailers who illegally sold ENDS products to minors;[2] (3) in January 2019, holding a public hearing to discuss strategies to eliminate youth use of ENDS with a focus on the role of drug therapies to help young people quit using e-cigarettes and other tobacco products;[3] (4) in March and April 2019, publicly admonishing thirteen national chain stores and franchises with high rates of violations for illegal sales of tobacco products to minors, and requesting plans that describe how these retailers will address and mitigate illegal sales to minors;[4] (5) in June 2019, sending four warning letters jointly with the Federal Trade Commission for violations related to online posts by social media influencers;[5] and (6) continuing robust public education efforts to prevent youth use of tobacco, including expanding its tobacco prevention campaign—called "The Real Cost"—to ENDS products with messaging that has been seen by teens nearly 500 million times.[6] Other CTP actions to address youth use are described in a March 2019 draft

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[1] *See* FDA News Release, *available at* https://www.fda.gov/news-events/press-announcements/fda-warns-more-companies-stop-misleading-kids-e-liquids-resemble-kid-friendly-foods-part-youth.

[2] *See* FDA News Release, *available at* https://www.fda.gov/news-events/press-announcements/fda-takes-new-steps-address-epidemic-youth-e-cigarette-use-including-historic-action-against-more.

[3] *See* Eliminating Youth Electronic Cigarette and Other Tobacco Product Use: The Role for Drug Therapies Public Hearing, Jan. 18, 2019, https://www.fda.gov/news-events/fda-meetings-conferences-and-workshops/eliminating-youth-electronic-cigarette-and-other-tobacco-product-use-role-drug-therapies-public.

[4] *See* https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-forceful-new-actions-focused-retailers-manufacturers.

[5] *See* https://www.fda.gov/news-events/press-announcements/fda-ftc-take-action-protect-kids-citing-four-firms-make-sell-flavored-e-liquids-violations-related.

[6] *See* https://www.fda.gov/tobacco-products/public-health-education-campaigns/real-cost-campaign.

guidance document.[7]

5. This case relates to the premarket review of deemed tobacco products that are new tobacco products as defined in 21 U.S.C. § 387j(a)(1). I describe the various pathways in which tobacco products may be legally marketed below:

a. Grandfathered Tobacco Products. Products that were commercially marketed in the United States as of February 15, 2007, are considered "grandfathered" and do not require prior authorization to be legally marketed. *See* 21 U.S.C. § 387j(a)(1). They also may serve as a predicate tobacco product for a substantial equivalence (SE) report, described below. FDA has made 1,651 grandfathered determinations for deemed products (e.g., cigars, pipe tobacco, and waterpipe tobacco).[8] Seeking an FDA grandfather determination is a voluntary process and there are likely many additional grandfathered products being marketed.

b. Substantial Equivalence (SE). A substantially equivalent tobacco product is a new tobacco product that has been found by FDA either to have the same characteristics as a predicate tobacco product or to have different characteristics than the predicate tobacco product, but, in the latter case, the substantial equivalence report submitted by the manufacturer demonstrates that it is not appropriate to regulate the new tobacco product under the Premarket Tobacco Application (PMTA) pathway because the product does not raise different questions of public health. 21 U.S.C. § 387j(a)(3)(A). A predicate tobacco product that an applicant can use is one that was commercially

[7] *See* Modifications to Compliance Policy for Certain Deemed Tobacco Products, Draft Guidance (Mar. 2019) at 5, *available at* https://www.fda.gov/media/121384/download.
[8] *See* Grandfathered Tobacco Products, *available at* https://www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/grandfathered-tobacco-products (page last viewed June 12, 2019).

marketed in the United States as of February 15, 2007 (a grandfathered tobacco product), or has previously been found to be substantially equivalent by FDA, and is in compliance with the requirements in Chapter IX of the FDCA. FDA has issued guidance documents[9] and a proposed rule on April 2, 2019,[10] which address SE reports. As of April 30, 2019, FDA has authorized 1070 products with SE orders. For deemed products, FDA has received 313 SE reports and issued four orders authorizing SE reports.[11]

c. Substantial Equivalence Exemption. A new product may be exempt from the need to demonstrate substantial equivalence if it is modified by adding or deleting a tobacco additive or by increasing or decreasing the quantity of an existing tobacco additive, and such a modification would be a minor modification of a legally marketed product and an SE report is not necessary for the protection of public health. 21 U.S.C. § 387e(j)(3). As of April 30, 2019, FDA has issued 199 SE exemption orders, including 21 orders for deemed products.[12] FDA issued a final rule establishing procedures for requesting an exemption from the substantial equivalence requirements in 2011. *See* 76 Fed. Reg. 38,961 (Jul. 5, 2011). In addition, information about this pathway is available in the SE guidance documents referred to above.

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[9] *See* Section 905(j) Reports: Demonstrating Substantial Equivalence for Tobacco Products (Jan. 2011), available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/section-905j-reports-demonstrating-substantial-equivalence-tobacco-products. FDA has also issued another Guidance, Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions, most recently revised in December 2016 (available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/demonstrating-substantial-equivalence-new-tobacco-product-responses-frequently-asked-questions).

[10] *See Content and Format of Substantial Equivalence Reports; Food and Drug Administration Actions on Substantial Equivalence Reports*, 84 Fed. Reg. 12740 (Apr. 2, 2019).

[11] *See* https://www.fda.gov/tobacco-products/substantial-equivalence/marketing-orders-se (Jan. 29, 2019 order for Black & Mild Shorts). SE orders are generally publicly available at the website above, but commercially confidential information must be redacted before posting. Three of the four SE orders referred to above have not yet been posted.

[12] *See* SE Exemption Order for John Middleton Co., Black & Mild (Sept. 7, 2018), *available at* https://www.fda.gov/tobacco-products/exemption-substantial-equivalence/marketing-orders-exemption-se.

d. Premarket Tobacco Application (PMTA). All other new tobacco products must be authorized through the PMTA pathway, which requires applicants to demonstrate that the new tobacco product is appropriate for the protection of the public health, which is determined with respect to the risks and benefits to the population as a whole, including users and non-users of tobacco products, and taking into account the increased or decreased likelihood that existing users of tobacco products will stop using such products, and those who currently do not use tobacco products will start using such products. 21 U.S.C. § 387j(b), (c). FDA issued a guidance specifically for ENDS products, which are likely to be reviewed through the PMTA pathway, on June 11, 2019 ("PMTAs for ENDS Guidance").[13] The PMTAs for ENDS Guidance is intended to assist applicants to prepare PMTAs for these products and explains, among other things, when a PMTA is required, general procedures for review of an ENDS PMTA, what information the FDCA requires applicants to submit in a PMTA, and what information FDA recommends applicants submit in an ENDS PMTA to show whether permitting such new tobacco product to be marketed is appropriate for the protection of the public health. In addition, FDA intends to issue a proposed rule in the near future to further specify application contents and FDA's review and communication procedures under this pathway.[14] As of April 30, 2019, FDA has received 401 PMTA applications, 373 of which are for deemed products. FDA has authorized the marketing of 12 total products

[13] *See* Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems Guidance for Industry (June 2019), *available at* https://www.fda.gov/regulatory-information/search-fda-guidance-documents/premarket-tobacco-product-applications-electronic-nicotine-delivery-systems-ends.
[14] *See* Premarket Tobacco Product Application and Recordkeeping Requirements, RIN: 0910-AH44, *available at* https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201904&RIN=0910-AH44.

under two different product types (non-combustible cigarettes and smokeless tobacco),[15] and closed out 369 of the 373 applications it has received for deemed products as insufficient to accept or file, primarily for failure to file an adequate environmental assessment, as required by 21 C.F.R. § 25.15. Only four PMTA applications are pending with the agency at this time for deemed products, none of them for an ENDS product. Thus far, FDA has provided information about the PMTA application process through public seminars and workshops,[16] and regularly meets with sponsors to discuss FDA's expectations for these applications.

6. By statute, all deemed products require marketing authorization unless they are grandfathered. No deemed products had authorization when the deeming rule went into effect. Thus, when the deeming rule took effect on August 8, 2016, all deemed products on the market were suddenly noncompliant with the statute. Accordingly, in the preamble to the deeming rule, FDA announced a compliance policy under which, as an exercise of enforcement discretion, it intended to defer enforcement of various provisions for limited periods of time to give manufacturers time to come into compliance. With respect to premarket review, for products that were on the market as of August 8, 2016, FDA provided staggered compliance dates for submission of applications depending on the type and complexity of the application; in addition, if an application was submitted within the compliance period, the preamble further stated that the agency did not intend to initiate enforcement for lack of a marketing order from FDA for one year after submission while FDA reviewed the application. *Id.* at 28,977-78. As explained in the preamble, this policy was based on balancing complex and competing public health and resource

[15] *See* Premarket Tobacco Product Marketing Orders, *available at* https://www.fda.gov/tobacco-products/premarket-tobacco-product-applications/premarket-tobacco-product-marketing-orders.
[16] *See* Useful Links for PMTA, *available at* https://www.fda.gov/media/101179/download (Oct. 17, 2016).

considerations, primarily that products would remain available without having undergone scientific review, concerns regarding the effect that flavors have on use of tobacco products by youth and young adults, the potential for some net public health benefits if flavored ENDS remain available, the different risks posed by different classes of products, the fact that some flavored combusted products are grandfathered, the expected complexity of applications, efficiently managing the flow of incoming applications, and encouraging high-quality applications. *Id.*

7. In July 2017, FDA announced a new comprehensive approach to tobacco and nicotine. The approach included many components, the centerpiece of which was developing a regulation aimed at reducing nicotine in cigarettes to minimally addictive or non-addictive levels. In a world where cigarettes were minimally addictive or non-addictive, access to alternative and less harmful forms of nicotine would be essential. Other components included advancing rules to lay out what needs to be in SE and PMTA applications; determining whether and how FDA should regulate youth-appealing flavors in ENDS and other tobacco products; and seeking new information that may inform consideration of the regulation of so-called premium cigars. As one part of this comprehensive public health package, where each component was intended to work alongside the others in striking an appropriate balance, FDA stated that it would further defer enforcement of the premarket review provision for deemed products to encourage development of innovative tobacco products that had the potential to be less dangerous than cigarettes and to provide manufacturers additional time to develop higher quality applications informed by additional guidance and rules and products standards from the agency.

8. On August 8, 2017, FDA issued a revised guidance extending the compliance dates for the submission of premarket review applications for deemed products until August 8,

2021, for combustible new tobacco products (including cigars) and until August 8, 2022, for noncombustible new tobacco products (including most ENDS products)—but only for products that were on the market as of August 8, 2016. *See* Guidance for Industry: Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule (Aug. 2017) ("Guidance"). The Guidance also indicated that FDA expected that these products would remain on the market while their premarket applications were under review (or were withdrawn).

9. In the summer of 2018, data from the annual National Youth Tobacco Survey showed a significant increase in youth use of ENDS products. This followed two years of a reduction or leveling off in youth ENDS prevalence rates. These data prompted FDA to consider revising the compliance policy for premarket review set forth in the Guidance. On March 13, 2019, FDA issued a draft guidance proposing to modify that compliance policy.[17] This new draft guidance reiterated that all deemed products without a marketing order (except "grandfathered" products on the market as of February 15, 2007) were on the market in violation of the statute and therefore potentially subject to enforcement. It outlined FDA's enforcement priorities to help address youth use, particularly youth use of certain flavored products. The draft guidance reflects a careful rebalancing of public health considerations based on new information. It revises the prior deferred-enforcement policy with respect to broad categories of e-cigarette and cigar products, and proposes prioritizing enforcement of the premarket review provisions against: e-cigarette products targeted to minors or likely to promote use by minors; flavored e-cigarette products (except tobacco, mint, and menthol flavors) offered for sale in ways that pose heightened risks of youth access; flavored e-cigarette products (except tobacco, mint, and menthol flavors) offered for domestic sale after August 8, 2021, for which the manufacturer has

[17] *See* Modifications to Compliance Policy for Certain Deemed Tobacco Products, Draft Guidance (Mar. 2019) at 5, *available at* https://www.fda.gov/media/121384/download.

not submitted a premarket application; and flavored cigars. Evidence shows that tobacco, mint and menthol flavors are preferred more by adults than minors, and in the draft guidance FDA noted it is concerned by the potential that adult former smokers who switched to ENDS could be at risk of migrating back to combustible products if there were an abrupt market exit of ENDS.[18]

Remedies

10. FDA has continued to invest significant resources into addressing the recent surge in youth ENDS use and developing the draft March 2019 guidance, and is committed to finalizing the guidance within 120 days. FDA has thus far received over 15,000 comments on the draft guidance and has reviewed the more substantial comments. FDA expects to complete consideration of the comments, draft the final guidance, and publish it on this highly accelerated 120-day timeframe.

11. The general framework of the March 2019 guidance, when finalized, would allow FDA to strike an appropriate balance of complex and competing public health and agency resource considerations, including addressing the rapid rise in youth use of ENDS versus the availability of potentially less harmful products for currently addicted adult users of combustible products. I believe that finalizing this guidance – which focuses on restricting youth access to flavored ENDS products – is one of the most critical public health steps that FDA can take to curb youth vaping.

12. I understand that plaintiffs seek a remedy that would order FDA "to ensure that no new tobacco product" that was subject to the Guidance's extended compliance dates "may

[18] *See* Schneller, L.M., M. Bansal-Travers, M.L. Goniewicz, et al., "Use of flavored electronic cigarette refill liquids among adults and youth in the US—Results from Wave 2 of the Population Assessment of Tobacco and Health Study (2014-2015)," *PLoS ONE* 13(8): e0202744 (2018), available at: https://doi.org/10.1371/journal.pone.0202744; Harrell, M.B., Weaver, S. R., Loukas, A., et al., "Flavored e-cigarette use: Characterizing youth, young adult, and adult users. *Preventive Medicine Reports*, 5, 33-40, (2017), doi: 10.1016/j.pmedr.2016.11.001.

remain on the market without being subject to FDA enforcement action" unless an application for premarket review has been received within 120 days of a remedial order from the Court. It is my firm belief that plaintiffs' proposed 120-day submission deadline creates a genuine risk of migration from potentially less harmful ENDS products back to combustible tobacco products within the population of addicted adult smokers who have completely switched to ENDS. This is a public health outcome that should be avoided if at all possible, while still achieving the public health benefits of earlier premarket review for deemed products, especially with respect to curtailing youth use.

13. If the Court nevertheless finds it necessary to enter an injunction requiring the submission of premarket applications by a date certain, it should not set a deadline sooner than 10 months from now—a date that I believe would at least make it feasible for more manufacturers to develop and submit complete and high quality applications, and for FDA to publish a proposed PMTA rule and be close to finalizing the SE and PMTA rules. It would also enable ENDS manufacturers to consider and strengthen their applications based on the final PMTA for ENDS guidance. Similarly, if the Court enters an injunction limiting the compliance period for products with timely premarket applications on file to one year, as Plaintiffs also request, it should not disturb the FDA's discretion to defer enforcement on a case-by-case basis with respect to applicants who have provided the needed information and made substantial progress toward completion, as was the case under the original compliance policy. *See* 81 Fed. Reg. at 29,012.

14. This approach, although not as accelerated as Plaintiffs' proposal, would better protect the public health. Products lacking an application after 10 months would be subject to enforcement, as would products lacking an authorization after a one-year review period.

Critically, in the interim, all deemed new products would be subject to enforcement in accordance with the priorities set forth in the March 2019 draft guidance, when finalized, even before the 10-month submission and one-year review time periods elapse.

15. Plaintiffs' proposed remedy, by contrast, would cause significant public health concerns, as well as implementation challenges. First and foremost, from the public health perspective, Plaintiffs seek to clear the market of any new and unauthorized deemed products for which no application is submitted within 120 days. Given the nearness of that deadline and the very limited number of companies (fewer than 10) that have sought pre-submission meetings with FDA to discuss potential premarket applications for ENDS products, I believe that, if plaintiffs' proposed remedy were granted, it is likely that there would be a mass market exit of ENDS products. For cigarette smokers who completely switch to ENDS, these products may be less harmful at an individual level than combustible tobacco products. It is possible some of these products may have a net positive effect on public health at a population level, depending on several factors, including patterns of use. Overall population level impact remains uncertain today, especially given youth uptake of ENDS. We do not yet know the general public health impact of these products, but it is likely that some ENDS products may reduce harm at the individual level and that some addicted adult smokers use these products with a goal to end use of combustible tobacco products. Given this, mass market exit of such products would limit the availability of a potentially less harmful alternative for adult smokers seeking to transition or stay away from combustible tobacco products. Dramatically and precipitously reducing availability of these products could present a serious risk that adults, especially former smokers, who currently use ENDS products and are addicted to nicotine would migrate to combustible tobacco products, even if particular ENDS products ultimately receive marketing authorization and return

to the market later. And, although there has been great recent progress in declining use of cigarettes for all age groups, I am concerned that these declines could be slowed or reversed in the case of very sudden and very dramatic reductions in availability.

16. Second, there are important programmatic and logistical considerations. Of course, manufacturers may submit premarket applications for these products at any time, and there is no legal barrier to filing. Indeed, CTP has accepted, filed and authorized applications through each of the available pathways based on statutory criteria even in the absence of rules or product-specific guidance. However, I am concerned that many ENDS manufacturers will be unlikely to submit quality PMTA applications (*e.g.*, applications that are sufficiently complete and organized to enable CTP to efficiently conduct the required scientific review) for deemed products within a 120-day period. Instead, a longer period of time (10 months) would be appropriate to help ensure that manufacturers are better able to prepare quality submissions. Their efforts will be aided by FDA's publication of the PMTAs for ENDS Guidance, which provides important recommendations to help this newly regulated segment of industry develop their applications. Most significantly, that guidance describes the types of information required by the statute for submission in a PMTA, provides recommendations for how to address specific public health concerns, and suggests ways to demonstrate that a product is appropriate for the protection of public health. I am concerned that 120 days is an insufficient amount of time to permit some manufacturers to consider and implement the recommendations in the guidance.

17. In addition, there will also be logistical impediments for CTP to receive and review large numbers of applications without being able to meaningfully prioritize among them. The Final Regulatory Impact Analysis (RIA) from 2016 estimates that manufacturers will apply for marketing authorization for 5,424 to 6,764 deemed products (of all types) in the initial

compliance period (two years). AR 23,995 (RIA at 84). Of these, an estimated 1,250 to 2,000 would be PMTAs for e-liquids, as well as 360-450 for ENDS delivery devices. *Id.* These numbers are based on estimates in the context of significant uncertainty, and it is possible that manufacturers will seek premarket authorization for many more products, particularly if the products' continued marketing is contingent on the filing of an application. One concern here is that low-quality applications, many of which could be time-consuming to review due to their poor quality, will be submitted merely to prolong marketing.

18. For ENDS PMTAs, these are first-ever applications for a previously novel and unregulated category of products. Thousands of these applications are expected to be submitted very close in time. This expectation is based on the dynamics of the deadline coming earlier than many applicants previously anticipated. It is also informed by our experience with provisional SE applications, as discussed below. Many applicants will be newly regulated entities lacking experience with FDA, and based on our experience to date, the applications are anticipated to be lower in quality and less complete than current-day applications for other FDA regulated products. A large volume of incomplete or haphazard applications in which the information is not clearly presented or is missing data will cause further delay because it will divert valuable agency resources into the painstaking effort of reviewing those submissions and communicating deficiencies. In addition, there may be technological challenges to accepting and processing large applications if they come in all at once, especially if the deadline were as soon as 120 days after a court order, allowing FDA less time to continue preparations.

19. For comparison, in 2011, at a parallel point in time with a submission deadline approaching, approximately 3,000 of 3,600 provisional SE applications were submitted within

the last several days leading up to a March 22, 2011 deadline.[19] While FDA has put many more systems in place since then, and has created a robust application review process within CTP's Office of Science, there is no doubt that the agency will be flooded with applications in the final days leading up to any court-ordered submission deadline. I expect that FDA will receive roughly 5,424 to 6,764 applications for three different authorization pathways. This will undoubtedly put a strain on the agency. Additional time to file applications would provide more planning time for FDA and applicants, more time to build out operational systems, and more time to issue guidance and rules to reduce the volume of low-quality applications.

20. Most ENDS products are relatively novel and are unlikely to be substantially equivalent to a valid predicate and so will need to be authorized through the PMTA pathway. Among other things, a PMTA application must include:

a. Full reports of all information concerning investigations which have been made to show the health risks of the new tobacco product and whether such product presents less risk than other tobacco products;

b. Full statement of the components, ingredients, additives, and properties, and of the principle(s) of operation of the new tobacco product; and

c. Full description of the methods used in, and the facilities and controls used for, the manufacture, processing, packing and installation of the new tobacco product.

21. In addition, some applications may need new nonclinical and clinical studies if the product's potential impact on the public health has not yet been sufficiently reviewed, though in some cases it may be possible to support a marketing order for an ENDS product without

[19] *See* FDA Update on Provisional Substantial Equivalence (SE) Review Process (Apr. 5, 2018), *available at* https://www.fda.gov/tobacco-products/ctp-newsroom/fda-update-provisional-substantial-equivalence-se-review-process.

conducting new nonclinical or clinical studies. For example, if there is an established body of evidence regarding the health impact (individual or population) of a product or a similar product that can be adequately bridged to product that is the subject of the application, such as data from the published literature or government-sponsored databases, these data may be sufficient to support a PMTA.

22. Plaintiffs' proposed 120-day deadline for the submission of premarket applications does not account for the sheer number of expected applications, the complexity of those applications and the scientific review process, or the public health and operational concerns I have described. I believe that a submission deadline at least 10 months away would reflect a much better balancing of the competing concerns and, though still accelerated, would at least reduce the potential for administrative disruption and the risk of a mass market exit that could adversely affect the public health.

I declare under penalty of perjury that the foregoing is true and correct to the best of my information, knowledge, and belief.

Dated: Silver Spring, Maryland

June 12, 2019

Mitchell Zeller -S

Digitally signed by Mitchell Zeller -S
Date: 2019.06.12 23:08:03 -04'00'

Mitchell Zeller
Director, Center for Tobacco Products
United States Food and Drug Administration