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April 6, 2021

The Honorable Mitch Zeller
Director
Center for Tobacco Products
U.S. Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, Maryland 20993

Dear Director Zeller:

We are conducting oversight of the U.S. Food and Drug Administration (FDA)'s Center for Tobacco Product's (CTP) processes and procedures for reviewing tobacco product applications. Because of the voluminous number of "new tobacco product" applications submitted to CTP last year, we are interested in learning more about what actions CTP is taking to finalize review of the applications before the September 9, 2021 court ordered deadline for deferring enforcement actions.[1]

The FDA issued a final rule in 2016 requiring all new tobacco products to obtain premarket authorization.[2] Through the premarket review process, "FDA conducts a science-based evaluation to determine whether a new tobacco product meets the applicable statutory standard for market authorization."[3] For example, whether the "product is appropriate for the protection of public health with respect to the risks and benefits to the population as a whole."[4] In 2019, the U.S. District Court for the District of Maryland directed FDA to require premarket authorization applications for all new tobacco products to be submitted to FDA by May 12,

[1] Mitch Zeller, *Perspective: FDA's Progress on Review of Tobacco Product Applications Submitted by the Sept. 9, 2020 Deadline*, U.S. Food and Drug Administration, Feb. 16, 2021, *available at* https://www.fda.gov/tobacco-products/ctp-newsroom/perspective-fdas-progress-review-tobacco-product-applications-submitted-sept-9-2020-deadline.
[2] U.S. Food and Drug Administration, *Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization (Revised)*, April 2020, *available at* https://www.fda.gov/media/133880/download.
[3] *Id.*
[4] *Id.*

2020.[5] The court also provided a one-year period for products to remain on the market pending FDA review.[6] Due to COVID-19, the deadline for applications was extended until September 9, 2020.[7]

As of now, FDA must complete review of the applications before September 9, 2021 because it will no longer be able to defer enforcement actions after that date. According to CTP, the agency has received over 4.8 million premarket tobacco product applications from 230 companies, a substantial number of applications to review in one year.[8] This raises questions about whether CTP has the ability to fully complete review and what happens to the products that are neither approved or rejected by FDA before the deadline.

While it appears that CTP is working diligently to review applications, we are concerned about what policies and procedures are in place to ensure that applications are reviewed before the upcoming September deadline. Given the impact of the COVID-19 pandemic throughout the country, we want to ensure that proactive steps are being taken so applications are at least accepted or rejected based on their merits by FDA to prevent any applications from being rejected simply because CTP was not able to conduct a review. It would be particularly troubling for a regulatory process to prevent some products from existing simply because a government agency did not have time for review.

Please make arrangements to schedule a briefing with Committee staff on this matter no later than April 13, 2021. We look forward to hearing about what policies and procedures are in place to ensure that CTP's regulatory process will allow for review of new applications by the September 2021 court ordered deadline. To schedule the briefing or ask any follow-up or related questions, please contact Committee on Oversight and Reform Republican staff at (202) 225-5074. Thank you in advance for your cooperation with this matter.

The Committee on Oversight and Reform is the principal oversight committee of the U.S. House of Representatives and has broad authority to investigate "any matter" at "any time" under House Rule X. Thank you in advance for your cooperation with this inquiry.

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[5] *American Academy of Pediatrics, et al. v. Food and Drug Administration, et al.*, 379 F. Supp. 3d 461, 496 (D. Md. 2019).
[6] U.S. Food and Drug Administration, *supra* note 2.
[7] *American Academy of Pediatrics et al., v. U.S. Food and Drug Administration et al. (2018)*, Public Health Law Center at Mitchell Hamline School of Law, *available at* https://www.publichealthlawcenter.org/content/AAP-v-FDA-2019, (last visited April 1, 2021).

[8] Zeller, *supra* note 1.

Sincerely,

James Comer
Ranking Member
Committee on Oversight and Reform

cc: The Honorable Carolyn Maloney, Chairwoman
Committee on Oversight and Reform