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Sarah Kotler
Director, Office of the Executive Secretariat
US Food & Drug Administration
5630 Fishers Lane, Room 1050
Rockville, MD 20857

E-mail: FDAFOIA@fda.hhs.gov.

Re: **FDA Freedom of Information Act Appeal**

FOIA Control # 2022-2523

Complete Technical Project Lead Decision Summary for the Marketing Granted Orders for Logic Technology products with the following STNs: PM0000529.PD1, PM0000530.PD1, PM0000531.PD1, PM0000535.PD1, PM0000536.PD1, PM0000537.PD1, PM0000540.PD1, and PM0000541.PD1

I am writing to appeal your decision to deny my request for expedited processing of the above referenced FOIA request.

The requested report is one 56-page document that is dated March 23, 2022, and signed or issued by Megan Schroeder, PhD. Previously, FDA has posted Technical Project Lead Decision Summaries (TPLs) for every Marketing Granted Order issued under the premarket tobacco product application (PMTA) process and for every Modified Risk Granted Order issued under the modified risk tobacco product application (MRTPA) process. However, for unexplained reasons, FDA failed to post the TPL for the subject Modified Granted Orders, but instead posted a four-page excerpt from its Executive Summary. This excerpt provides little information about FDA's analyses and decision-making processes and is therefore unsatisfactory.

The Technical Project Lead Decision Summary explains how and why FDA reached a determination that products that are the subject of the Marketing Granted Orders are appropriate for the protection of the public health. These decision summaries provide critical information for the public, scientists, and public health researchers about FDA's decision-making process and are essential for ensuring that the public, scientists, and researchers have confidence that the FDA is indeed protecting the public health. By withholding the full TPL report, FDA is eroding that confidence and raising suspicions that it has something to hide.

It is urgent that FDA provide the requested report because the FDA is currently poised to issue decisions on whether to grant permissive marketing orders for the e-cigarette products that are

the most popular with youth and that enjoy the greatest market share, and it is essential that the public understand how these decisions are made.

Disclosure of the requested information to me is in the public interest and will promote the objectives of the FDA and the Family Smoking Prevention and Tobacco Control Act. Pursuant to 21 CFR §20.44(a)(2), I am entitled to expedited processing because: (1) as an academic researcher I am primarily engaged in disseminating information to the general public; (2) there is an urgent need to obtain this information so that researchers can determine whether the authorized products are appropriate for the protection of the public health, to understand how FDA reached its determination, and to provide insight into how FDA is likely to make these determinations for future PMTAs; and (3) this request specifically concerns identifiable activities of the FDA, an agency of the Federal Government.

Additionally, there is an urgent need to obtain this information well before the May 15, 2022, letter of intent and the July 14, 2022, application deadline for the Tobacco Centers of Regulatory Sciences (TCORS) renewal applications for TCORS funding pursuant to RFA-OD-22-004 to understand how our proposed research could best inform FDA's regulatory decisions. The importance of this information to TCORS researchers was emphasized in one of the slides presented at FDA's March 21, 2022, Pre-Application Webinar for Tobacco Centers of Regulatory Science (TCORS) by Dr. Dana van Bemmel, Chief of Research Operations and Advisory Resources Branch, Office of Science, Center for Tobacco Products. Dr. van Bemmel urged potential applicants to consider "MRTPA & PMTA submissions" to better understand what "regulatory decisions could potentially be made" based on applicants' proposed research. However, although FDA makes Modified Risk Tobacco Product applications (MRTPAs) available to the public, it does not post or make available the PMTAs. Therefore, the only way researchers can try to understand FDA's regulatory process and ways of evaluating PMTAs is to have access to FDA's TPL decision summaries.

Finally, providing this single, clearly defined, 56-page document should not require FDA to spend significant time or resources and would not be overly burdensome to FDA staff.

Thank you for consideration of this reasonable appeal. It is essential that FDA is held accountable for its decisions and that its decision-making processes remain transparent.

Sincerely,

Lauren Kass Lempert