CITY AND COUNTY OF SAN FRANCISCO

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Via U.S. Mail and Fax

Food and Drug Administration
Division of Freedom of Information
Office of the Executive Secretariat, OC
5630 Fishers Lane, Room 1035
Rockville, MD 20857

Fax Number: (301) 827-9267

Re: Freedom of Information Act Request by the City and County of San Francisco

This is a request under the Freedom of Information Act, 5 U.S.C. § 552, for information and documents related to the decision by the Food and Drug Administration (the "FDA") to grant e-cigarette manufacturers until 2022 to submit their applications for premarket review. This request is made by the City and County of San Francisco ("San Francisco"). San Francisco also requests that the processing of this request be expedited, and that all fees associated with this request be waived.

This request concerns information of vital and urgent importance to the public. Tobacco use is the leading cause of preventable disease and death in the United States. Tobacco kills more than 480,000 people annually—more than AIDS, alcohol, car accidents, illegal drugs, murders and suicides combined. And nearly all tobacco product use begins during youth or young adulthood. As a result, the Surgeon General, local governments, health advocates and others have undertaken enormous efforts to reduce youth tobacco use. Until recently those efforts were succeeding. Cigarette smoking among youth had steadily declined over the past two decades. The percentage of middle and high school students using conventional cigarettes and other tobacco products was at an all-time low in 2017. But last year tobacco use among youth rose for the first time since the 1990s. According to the Centers for Disease Control and Prevention, the number of middle and high school students who reported being current users of tobacco products increased 36%—from 3.6 million to 4.9 million students—between 2017 and 2018. This dramatic reversal is directly attributable to a surge in e-cigarette use by adolescents.

Nonetheless, the FDA has given manufacturers of e-cigarettes until August 2022 to submit applications for premarket review, allowing a class of products that were known to be appealing to kids to stay on the market without any review. This means that by the time e-cigarette manufacturers will be required to submit their applications, e-cigarettes—which first emerged in 2007—will have been on the market for *fifteen years* without any FDA analysis of their safety and alleged benefit.

Accordingly, San Francisco requests copies of any and all records created on or after May 10, 2016, that discuss, identify or evaluate:

(1) whether to extend the compliance date for "new, newly deemed finished [noncombustible] tobacco products that were on the market as of August 8, 2016"—including electronic nicotine delivery systems ("ENDS")—to August 8, 2022 as set forth in Table 2 of "Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule" and

(2) whether to accelerate the compliance date for any ENDS to a date earlier than August 8, 2022.

Additionally, San Francisco requests a waiver of all fees for this request. Disclosure of the information described in this request is in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the government. *See* 5 U.S.C. § 552(a)(4)(A)(iii). In the event that its request for a fee waiver is denied, San Francisco is willing to pay fees for this request up to a maximum of $1,000. If you estimate that fees for this request will exceed $1,000, please inform me first. San Francisco seeks the information described in this request for noncommercial use; thus, fees for this request are limited to reasonable standard charges for document search and duplication. 5 U.S.C. § 552(a)(4)(A)(ii)(III).

This request qualifies for expedited processing. Requests "shall be processed on an expedited basis whenever it is determined that they involve . . . . [a] matter of widespread and exceptional media interest in which there exist possible questions about the government's integrity that affect public confidence." 28 C.F.R. § 16.5(e)(1), (e)(1)(iv). The request satisfies this standard. The agency's inaction and the resulting public health crisis have generated widespread media attention. *See, e.g.*, Angelica LaVito, *US Lawmaker Faults FDA Chief for Lax Oversight of Teen Vaping*, CNBC, https://www.cnbc.com/2019/02/27/us-house-lawmaker-faults-fda-chief-for-lax-oversight-of-teen-vaping.html (Feb. 27, 2019); Katelyn Newman, *CDC Blames Vaping for Teen Tobacco Use Spike*, U.S. News & World Report, https://www.usnews.com/news/health-news/articles/2019-02-11/cdc-blames-e-cigarettes-vaping-for-teen-tobacco-use-spike (Feb. 11, 2019).

San Francisco certifies that the information provided in this request is true and correct to the best of its knowledge. *See* 28 C.F.R. § 16.5(e)(3). If you have any questions regarding this request, please contact Deputy City Attorney Sara Eisenberg at (415) 554-4633. Please send all information released under this request to Ms. Eisenberg at the address below.

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Thank you for your prompt attention to this request.

Sincerely,

DENNIS J. HERRERA
City Attorney

cc: Mitch Zeller, Director Center for Tobacco Products