September 17, 2018

VIA ECF

Mark Langer
Clerk of the Court
U.S. Court of Appeals for the D.C. Circuit
333 Constitution Avenue, N.W.
Room 5205
Washington, D.C. 20001

Re: **Response to Rule 28(j) Letter**
Nicopure Labs, LLC v. Food and Drug Administration, No. 17-5196
(oral argument heard Sept. 11, 2018)

Dear Mr. Langer:

FDA's September 12 letter provides no new authorities and instead describes enforcement actions that have nothing to do with appellants and target only a portion of the e-cigarette industry.[1] FDA reports that to prevent e-cigarette use by minors, it has issued letters and fines to retailers, plans a national campaign to warn teenagers about nicotine risks, and is contemplating removing e-cigarettes that might be appealing to children from the market, among other actions.

Those enforcement actions prove appellants' point: If FDA is concerned about purchases by or marketing of e-cigarettes to youths, it can and should advance that interest through actions targeted at that problem (e.g., targeting "strawman" purchases by adults), not through a blanket prohibition on all truthful, non-misleading speech by manufacturers to adults. *See Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 371 (2002) ("[I]f the Government could achieve its interests in a manner that does not restrict speech, or that restricts less speech, the Government *must* do so.") (emphasis added). Combatting the use of e-cigarettes by minors through banning truthful speech to adults "is to burn the house to roast the pig" and would "reduce the adult population . . . to reading only what is fit for children"—in this case, nothing. *Butler v. Michigan*, 352 U.S. 380, 383 (1957).

[1] By "97 percent of the e-cigarette market," FDA apparently means only the "cartridge-based" market. The "open-tank" segment—which appellants' businesses primarily focus on—constitutes the majority of the e-cigarette marketplace.

Commissioner Gottlieb reiterated that FDA is "fully committed to the concept that products that deliver nicotine exist on a continuum of risk, with combustible products representing the highest risk, and [e-cigarettes] perhaps presenting an alternative for adult smokers who still seek access to satisfying levels of nicotine, but without all of the harmful effects that come from combustion." The MRTP preclearance requirement prevents manufacturers from conveying exactly the same truthful information about the "continuum of risk" endorsed by Commissioner Gottlieb in these remarks and by FDA in the Deeming Rule. It is thus more restrictive than necessary and undermines FDA's asserted public-health goals.

Sincerely,

/s/ Miguel A. Estrada

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CERTIFICATE OF SERVICE

I certify that on this 17th day of September 2018, I caused a true and correct copy of the foregoing letter to be served via electronic mail upon all counsel of record by operation of the Court's ECF system.

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