

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF COLUMBIA**

NICOPURE LABS, LLC,

Plaintiff,

v.

FOOD AND DRUG ADMINISTRATION;  
SCOTT GOTTLIEB, M.D., in his official  
capacity as Commissioner of Food and  
Drugs; and THOMAS E. PRICE, M.D., in  
his official capacity as Secretary of Health  
and Human Services,

Defendants.

Civil Action No. 16-878 (ABJ)

RIGHT TO BE SMOKE-FREE  
COALITION, *et al.*,

Plaintiffs,

v.

FOOD AND DRUG ADMINISTRATION;  
SCOTT GOTTLIEB, M.D., in his official  
capacity as Commissioner of Food and  
Drugs; and THOMAS E. PRICE, M.D., in  
his official capacity as Secretary of Health  
and Human Services,<sup>1</sup>

Defendants.

Civil Action No. 16-1210 (ABJ)

**JOINT NOTICE**

The parties respectfully notify the Court that the Food and Drug Administration (“FDA”) has announced that it is deferring enforcement of all future compliance deadlines under the

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<sup>1</sup> Pursuant to Fed. R. Civ. P. 25(d), Dr. Scott Gottlieb and Dr. Thomas Price are substituted for their predecessors in office.

Deeming Rule for three months, and has issued guidance to that effect. *See* <https://www.fda.gov/downloads/tobaccoproducts/labeling/rulesregulationsguidance/ucm557716.pdf>.

As described in the guidance, this deferral affects a subset of compliance deadlines under the Deeming Rule, including those for the submission of manufacturer registrations; product listings; ingredient listings; substantial equivalence (“SE”) reports, SE exemption requests, and premarket tobacco product applications (“PMTAs”) for products on the market as of August 8, 2016; and modified risk tobacco product (“MRTP”) applications for products with the descriptors “light,” “mild,” or “low” or similar descriptors, among other deadlines. Defendants represent that the deferral is intended to give new leadership personnel at the Department of Health and Human Services and the FDA an opportunity to more fully consider the issues raised by the deeming rule, given the pendency of other challenges where briefing has not yet begun or is in its early stages.<sup>2</sup>

This deferral does not affect deadlines that have already passed, such as the ban on the distribution of free samples challenged in this case. *See* Nicopure Compl. ¶ 55; RSF Compl. ¶¶ 90–100.

Plaintiff Nicopure Labs, LLC believes that this deferral is not a reason for the Court to withhold its decision on the pending cross-motions for summary judgment. Plaintiffs Right To Be Smoke-Free Coalition et al. do not join Nicopure in this last point. Defendants take no position on this point.

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<sup>2</sup> *See* *Lost Art Liquids v. FDA*, No. 16-3468 (C.D. Cal.); *Sanchez Icaza v. FDA*, No. 16-21967 (S.D. Fla.); *Cyclops Vapor 2 v. FDA*, No. 16-556 (M.D. Ala.); *Cigar Ass’n of Am. v. FDA*, No. 16-1460 (D.D.C.). In a sixth case, Defendants’ motion to dismiss for lack of jurisdiction is fully briefed. *See* *Faircloth v. FDA*, No. 16-5267 (S.D.W. Va.).

Dated: June 8, 2017

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Respectfully submitted,

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