

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

CIGAR ASSOCIATION OF AMERICA, <i>et al.</i>)	
)	
)	
Plaintiffs,)	
)	
v.)	Civil Action No. 16-1460 (APM)
)	
UNITED STATES FOOD AND DRUG ADMINISTRATION, <i>et al.</i> ,)	
)	
Defendants.)	
)	

JOINT STATUS REPORT

Pursuant to the Court’s August 16, 2018 status conference and November 8 and December 4, 2018 minute entries, the parties respectfully submit this Joint Status Report.

Joint Statement: At this time, the parties agree to further defer briefing of Counts I, IV, and V of the complaint in this case until January 14, 2019, at which time they propose submitting a further status report with respect to these claims. The parties set forth separate statements below.

Plaintiffs’ Statement: As noted at the August 16, 2018 status conference before the Court and in the November 1, 2018 status report, Plaintiffs are concerned about the impending November 8, 2019 deadline for reporting of harmful and potentially harmful constituent (“HPHC”) testing for all cigars and pipe tobacco. In the Deeming Rule itself, FDA promised guidance regarding HPHC reporting and a rule providing a methodology for HPHC testing, both well in advance of the November 8, 2019 date. 81 Fed. Reg. at 28,980, 29,051. That has not happened. According to the unified regulatory agenda, such a rule is not even in the agency’s pipeline. And even if it were published today, it would not be early enough, as the November 8, 2019 deadline is to report the results of testing thousands of cigar types, not to begin the testing itself. Moreover, the

pendency of FDA's premium cigar docket may obviate the HPHC testing and reporting requirements for premium cigars, but that docket will not be completed prior to the deadline. *See Cigar Ass'n of Am. v. U.S. Food & Drug Admin.*, 317 F. Supp. 3d 555, 563 (D.D.C. 2018) (quoting *Cigar Ass'n of Am. v. U.S. Food & Drug Admin.*, 315 F. Supp. 3d 143, 175 (D.D.C. 2018)).

An extension of the November 2019 deadline has been requested from FDA. Unless that extension is granted, Plaintiffs will need to bring claims challenging the HPHC testing and reporting requirement in January 2019. Options include seeking to amend the complaint, by consent or by motion, or filing a separate complaint before this Court.

With regard to the substantial equivalence and premarket review process and the arbitrary failure to appropriately treat the category of the premium cigars challenged in Counts I, IV, and V, Plaintiffs continue to monitor regulatory developments and are considering either continuing to stay those claims with the Court's permission or dismissing them without prejudice, assuming appropriate protections for future litigation are put in place by agreement with the Government or through Court order. Plaintiff associations will provide their respective views on the appropriate disposition of those claims in their January 14, 2019 status report.

Defendants' Statement: Defendants remain open to having the remaining claims in this case—i.e., Counts I, IV, and V of the complaint—either further deferred or dismissed without prejudice, as previously reported. *See* ECF No. 53, at 3; ECF No. 110, at 3; ECF No. 111, ¶ 2. Defendants have not received a proposal for “appropriate protections” for those claims in the event of dismissal, or for potential proceedings on any other, unpleaded claims, but will provide their views once Plaintiffs determine how they wish to proceed.

Dated: December 13, 2018

Respectfully submitted,

/s/ Michael J. Edney

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