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BY COURIER
AND VIA REGULATIONS.GOV

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. FDA-2014-N-0189; Request for Extension of Comment Period

Dear Sir or Madam:

The Cigar Association of America, Inc. (CAA) submits this request for an extension of the comment period in response to the Food and Drug Administration's (FDA's) Proposed Rule Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Regulations on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products, *see* 79 Fed. Reg. 23142 (April 25, 2014).

CAA requests a 75 day extension of the comment period for the proposed rule because the current 75 day comment period fails to provide sufficient time for meaningful, thorough responses to the many questions and issues raised by the proposed rule.[1] At the outset, FDA asks for comments on a vast number of questions covering at least fifteen discrete topics and approximately 70 cigar-specific matters. Responding to FDA's solicitation of comments on these many questions creates an enormous task. Moreover, the cigar industry, and we believe each affected industry, likely will raise additional issues that are not specifically

[1] In the device context, the FD&C Act describes 60 days as a minimum and allows up to an initial 90 days for comments prior to any discretionary agency enlargement of the comment period. See § 520(d)(2). We believe given the great amount of information FDA included in the proposed regulation, and the time the government spent in crafting and publishing the proposal, 90 days should have been granted at the outset and granting an additional 60 day extension would equal the total amount of time we now request. Although section 520(d) governs specified rulemakings in the device context, it provides appropriate guidance here for determining the length of a comment period for a proposed regulation that is accompanied by a relatively massive preamble and a regulation with such a large potential effect.

highlighted by the agency's inquiries in the proposal. Importantly, many of the issues that are presented in the proposed deeming rule are complex and require thorough review and analysis. For example, FDA is requesting comments on the impact of the premarket review process on newly deemed products. In addition, the agency also asks about whether it is appropriate to deem premium cigars subject to FDA regulation, and on how "premium cigar" should be defined to ensure that a possible exclusion from regulation would apply only to those cigars that, because of how they are used, may have less of a public health impact than other types of cigars. *See* 79 Fed. Reg. at 23150. These are complex questions that include the manufacturing method and composition of premium cigars, and the selling price of cigars that are almost universally considered premium. In other words, the permutations on the premium cigar definition issue are substantial and deserve the time it will take to respond to agency inquiries. Additionally, considering alternative approaches to FDA's proposed options, that are compatible with the agency's goals, also presents significant challenges.

FDA also solicits data/research on a number of issues, including on the long-term effects of flavored tobacco product usage and the likelihood of whether users of flavored tobacco products initiate cigarette usage and/or become dual users with cigarettes. *See* 79 Fed. Reg. at 23144. FDA also requests comments and data showing the extent to which a prohibition against free samples would reduce youth use of the proposed deemed products. *Id.* at 23149. These types of issues require research, data analysis, and possibly the identification and use of expert resources. Reviewing and analyzing research data is time-consuming and cannot be reasonably done within FDA's proposed timeframe.

On top of the foregoing challenges, meaningful responses to the proposed rule require a review and evaluation of the references that FDA relies upon in the proposal. FDA cites a total of 194 references in the proposed deeming rule, the review of which will be time-consuming. Although FDA states that the references are available at www.regulations.gov, as of the date of this letter, the references are not posted to the website and still remain unavailable from one source. As a result, industry only has 64 days remaining before the comments are due and to date has not had a chance to review the evidence upon which FDA relies for its deeming proposal. Without the opportunity to thoroughly review FDA's basis for the proposed rule, CAA and others will be unable to assess the strength of the evidence and comment meaningfully. In other words, the unavailability of the agency's basis for its proposal undermines the ability to comment, a situation not contemplated by the Administrative Procedure Act.

Even worse, it appears that not all of the evidence FDA relies upon in the proposed deeming regulation will be readily available and accessible within the proposed comment period. For example, FDA discusses in the proposed rule a recent analysis of cigar use by young adults that was presented at the meeting of the Society for Research on Nicotine and Tobacco. The agency cites this analysis as "preliminary confirmation" in support of the assertion that young adults use premium cigars. *See* 79 Fed. Reg. at 23151. Specifically, FDA states that the "analysis shows that current premium cigar use is being reported by young adults and that such use is not restricted to older adults." *Id.* The agency requests comment on this "evidence." To the extent this statement about premium cigar usage pertains to

consideration of Option 2, *i.e.*, excluding premium cigars from the effect of the deeming regulation, it is crucial for the premium cigar industry to be able to review and question FDA's data on premium cigar usage, and then respond to the agency suggestions or analysis with meaningful comments. However, the only publicly available information on this so-called "preliminary confirmation" is an opaque abstract from the meeting at which it was presented. This abstract fails to include the information the agency relies upon in the proposed rule. CAA contacted the Centers for Disease Control and Prevention (CDC) that conducted the survey upon which the proposed deeming regulation relies, and was advised that the CDC anticipate the data will be available early next spring. As a result, FDA is relying on information that will not be available for public scrutiny until after the comment period is closed.

A proposed deeming rule for cigars was first listed in the agency's regulatory agenda in December 2010. In an April 25, 2011 letter, Dr. Deyton expressed the agency's intention to propose a regulation that would extend the agency's authority to other categories of tobacco products that meet the statutory definition of tobacco product. This means that FDA has been working on the proposed deeming rule for close to four years, if not longer. Undoubtedly, this time period was necessary to conduct a review of the available evidence on general and youth usage of the proposed deemed tobacco products and to develop a framework for the regulation of the tobacco products. Granting tobacco product manufacturers, distributors, retailers and others interested in the rulemaking 2 ½ months to respond to a work product that required years is unfair, and will necessarily lead to incomplete and underdeveloped responses that will inadequately represent the comments necessary to ensure an equitable final rule that achieves the Tobacco Control Act's purpose.

CAA has not opposed regulation; indeed, we have worked cooperatively with the FDA to inform it about all aspects of the cigar industry. Nonetheless, we believe that any deeming regulation must be meaningful and practical. Establishing a regulatory framework for the proposed deemed tobacco products is a complex task that should not be rushed, although not unduly delayed. We therefore request that the comment period for the proposed deeming regulation be extended by 75 days.

CAA thanks FDA in advance for its consideration of this request.

Sincerely,

Craig P. Williamson

Craig Williamson
Cigar Association of America, Inc.