



May 4, 2018

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Division of Dockets Management
U.S. Food and Drug Administration
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Re: Docket No. FDA-2017-N-6107 (83 Fed. Reg. 12,901, Mar. 26, 2018) Advance Notice of Proposed Rulemaking on Regulation of Premium Cigars – Request for Extension of Comment Period

I write on behalf of the International Premium Cigar and Pipe Retailers Association (“IPCPR”) and Cigar Rights of America (“CRA”) in response to the Food and Drug Administration (“FDA”)’s March 26, 2018, Advance Notice of Proposed Rulemaking (“ANPRM”) regarding the regulation of premium cigars (Docket No. FDA-2017-N-6107).

IPCPR is a not-for-profit trade association serving the needs of premium cigar and retail tobacco shops throughout the United States and abroad. CRA is a non-profit association that acts as a voice for premium cigar manufacturers and consumers in the United States on matters of legislative and regulatory concern. IPCPR and CRA strongly support the FDA’s decision to reexamine the regulation of premium cigars. Both associations intend to gather data, consult with subject-matter experts, and provide detailed responses to the questions posed in the ANPRM. However, to achieve this end and to ensure that the agency bases its rulemaking on a complete record, IPCPR and CRA respectfully request that the FDA extend the current 90-day comment period for an additional 90 days, until September 24, 2018.

The ANPRM requests comments, data, and research on three broad topics: (1) the definition of premium cigars; (2) the use patterns of premium cigars; and (3) the public health considerations associated with premium cigars. Each topic includes three to fourteen questions, and many of the questions, in turn, contain a number of sub-questions. The question regarding an appropriate definition of premium cigars *alone* requests comments on eighteen discrete product characteristics. Between these questions, the agency has requested a great deal of scientific and industry data, much of which will require the work of experts to collect and interpret. If done in a manner that creates a well-informed and fulsome record for review, this process will last longer than 90 days.

We are grateful for the agency’s detailed inquiries, as they will aid in making sure that whatever is submitted is as useful as possible. Although the agency announced its intention to open this docket on July 28, 2017, it did not release the specific topics and questions on which submissions

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and data would be sought until March 26, 2018. IPCPR and CRA respectfully submit that the existing 90-day comment period does not provide the business community or the general public with sufficient time to assist the agency in building an appropriately informed and targeted record. It merits note that the FDA has prescribed longer comment periods for ANPRMs and proposed rules addressing similarly complex issues. For example, the FDA extended the comment period for the proposed Deeming Rule to 105 days (Docket No. FDA-2014-N-0189), extended the comment period for the ANPRM on the use of menthol in cigarettes to 120 days (Docket No. FDA-2016-N-0521), and extended the comment period for the proposed rule on N-nitrosornicotine levels in finished smokeless tobacco products to 165 days (Docket No. FDA-2016-N-2527).

CRA and IPCPR respectfully request an extension of the current comment period. CRA and IPCPR believe that a 90-day extension beyond the current deadline of June 25, 2018, would be appropriate under the circumstances and would serve the agency's interest in developing a thorough record for its rulemaking. CRA and IPCPR further ask that the agency endeavor to make a decision on this request as soon as possible, so that they can plan their efforts and ensure that their comments are fully responsive to the agency's inquiries.

Thank you very much for your consideration. We appreciate your prompt and careful attention to this request.

Very truly yours,

Michael J. Edney

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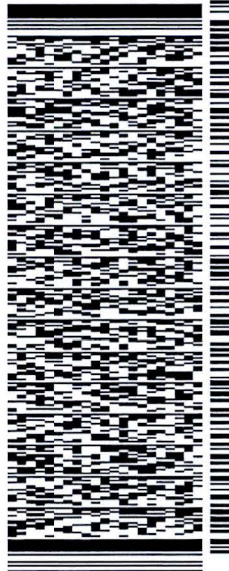
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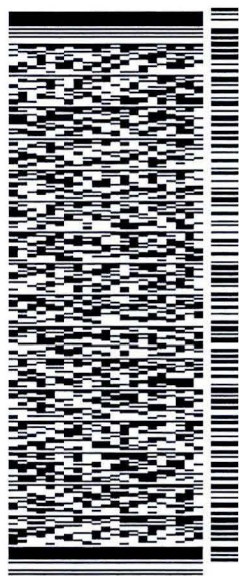
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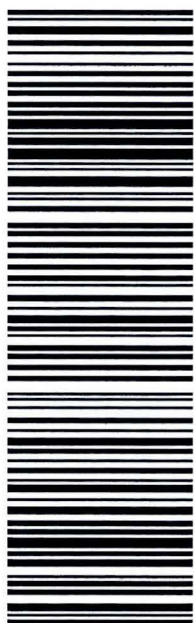
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