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Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, Maryland 20852

April 26, 2018

Re: *Docket No. FDA–2017–N–6107 (83 Fed. Reg. 12,901, March 26, 2018) Advance Notice of Proposed Rulemaking on Regulation of Premium Cigars — Request for Extension of Public Comment Period*

Davidoff of Geneva USA, Inc. ("Davidoff USA") writes in response to the March 26, 2018, Advance Notice of Proposed Rulemaking ("ANPRM"), by which FDA requests information related to regulatory actions FDA might take with respect to premium cigars under the Federal Food, Drug, and Cosmetic Act ("FD&C Act"). Comments are currently due by June 25, 2018. Given the comprehensive scope of the questions posed, Davidoff USA requests that FDA extend the 90-day comment period an additional 90 days, through September 23, 2018. The request is based on the following considerations.

The ANPRM seeks an all-encompassing, comprehensive response that seeks data, research results, and other information relating to premium cigars, in three separate categories. In the first category, while only three questions are listed relating to a definition of "premium" cigar, each question has various subparts; the second question alone has 18 subparts. In the second category, FDA poses seven questions, covering a broad range of issues relating to use patterns of premium cigars, including studies or other information. Finally, the third category requests studies or information on 14 separate issues on public health considerations relating to premium cigars. In total, there are 24 separate questions, with 18 identified subparts.

The ANPRM provides the public only 90 days to submit comments on these questions. The data and analysis FDA requests are voluminous and complex, and Davidoff USA requires additional time to gather the requested information and data, and analyze it, in order to prepare comments that will be useful to FDA in its deliberations on this important topic.

In previous issues of similar complexity, FDA provided longer comment periods. FDA ultimately provided 120 days to respond to its ANPRM on the use of menthol in cigarettes (Docket No. FDA-2013-N-0521), and 165 days to respond to its Proposed Rule on N-nitrosonornicotine ("NNN") levels in finished smokeless tobacco products (Docket No. FDA-2016-N-2527).

Further, FDA has not issued an ANPRM only on premium cigars. FDA also issued an ANPRM on the nicotine levels in combustible cigarettes, and asked whether the scope of that rule should include other combusted tobacco products, including cigars. (Docket No. FDA-2017-N-6189). FDA issued a third ANPRM requesting information relating to the regulation of flavors (Docket No. FDA-2017-N-6565). Davidoff USA needs sufficient time to analyze these additional ANPRMs as well.

Due to the complexity of the request, and the complexity of other requests made by FDA at the same time, Davidoff USA requests FDA provide an additional 90 days for public comments on the ANPRM. A ninety-day extension is appropriate given the breadth and importance of the issues addressed in the ANPRM. Additionally, we request that FDA consider and make a decision on this extension request as soon as possible, so that Davidoff USA can allocate resources accordingly and in an appropriate manner knowing the full timeline it will have to complete the comments.

Thank you for your consideration of our request.

James Young
President
Davidoff of Geneva USA, Inc.