NORTON ROSE FULBRIGHT

May 4, 2018

3518 18 MAY -7 A9:19

Division of Dockets Management
U.S. Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Norton Rose Fulbright US LLP
799 9th Street NW
Suite 1000
Washington, DC 20001-4501
United States

Direct line +1 202 662 0410
michael.edney@nortonrosefulbright.com

Tel +1 202 662 0200
Fax +1 202 662 4643
nortonrosefulbright.com

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

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-nitrosonornicotine 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

MJE

FOLD on this line and place in shipping pouch with **bar code and delivery address** visible

1. Fold the first printed page in half and use as the shipping label.
2. Place the label in a waybill pouch and affix it to your shipment so that the barcode portion of the label can be read and scanned.
3. Keep the second page as a receipt for your records. The receipt contains the terms and conditions of shipping and information useful for tracking your package.

Legal Terms and Conditions

Tendering packages by using this system constitutes your agreement to the service conditions for the transportation of your shipments as found in the applicable FedEx Service Guide, available upon request. FedEx will not be responsible for any claim in excess of the applicable declared value, whether the result of loss, damage, delay, non-delivery, misdelivery, or misinformation, unless you declare a higher value, pay an additional charge, document your actual loss and file a timely claim. Limitations found in the applicable FedEx Service Guide apply. Your right to recover from FedEx for any loss, including intrinsic value of the package, loss of sales, income interest, profit, attorney's fees, costs, and other forms of damage whether direct, incidental, consequential, or special is limited to the greater of 100 USD or the authorized declared value. Recovery cannot exceed actual documented loss. Maximum for items of extraordinary value is 500 USD, e.g. jewelry, precious metals, negotiable instruments and other items listed in our Service Guide. Written claims must be filed within strict time limits, see applicable FedEx Service Guide. FedEx will not be liable for loss or damage to prohibited items in any event or for your acts or omissions, including, without limitation, improper or insufficient packaging, securing, marking or addressing, or the acts or omissions of the recipient or anyone else with an interest in the package. See the applicable FedEx Service Guide for complete terms and conditions. To obtain information regarding how to file a claim or to obtain a Service Guide, please call 1-800-GO-FEDEX (1-800-463-3339).

FOLD on this line and place in shipping pouch with bar code and delivery address visible

1. Fold the first printed page in half and use as the shipping label.
2. Place the label in a waybill pouch and affix it to your shipment so that the barcode portion of the label can be read and scanned.
3. Keep the second page as a receipt for your records. The receipt contains the terms and conditions of shipping and information useful for tracking your package.

Legal Terms and Conditions

Tendering packages by using this system constitutes your agreement to the service conditions for the transportation of your shipments as found in the applicable FedEx Service Guide, available upon request. FedEx will not be responsible for any claim in excess of the applicable declared value, whether the result of loss, damage, delay, non-delivery, misdelivery, or misinformation, unless you declare a higher value, pay an additional charge, document your actual loss and file a timely claim. Limitations found in the applicable FedEx Service Guide apply. Your right to recover from FedEx for any loss, including intrinsic value of the package, loss of sales, income interest, profit, attorney's fees, costs, and other forms of damage whether direct, incidental, consequential, or special is limited to the greater of 100 USD or the authorized declared value. Recovery cannot exceed actual documented loss. Maximum for items of extraordinary value is 500 USD, e.g. jewelry, precious metals, negotiable instruments and other items listed in our Service Guide. Written claims must be filed within strict time limits, see applicable FedEx Service Guide. FedEx will not be liable for loss or damage to prohibited items in any event or for your acts or omissions, including, without limitation, improper or insufficient packaging, securing, marking or addressing, or the acts or omissions of the recipient or anyone else with an interest in the package. See the applicable FedEx Service Guide for complete terms and conditions. To obtain information regarding how to file a claim or to obtain a Service Guide, please call 1-800-GO-FEDEX (1-800-463-3339).