



July 24, 2018

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

RE: Docket No. FDA-2017-N-6107

Dear FDA Representative:

The National Association of Tobacco Outlets, Inc. (NATO) submits these comments in response to the Food and Drug Administration's Advanced Notice of Proposed Rulemaking titled "Regulation of Premium Cigars" as published in the Federal Register at 83 Fed. Reg. 12901 on March 26, 2018 (referred to in these comments as "Premium Cigar ANPRM").

Background on the National Association of Tobacco Outlets

NATO is a national retail trade association with approximately 60,000 member stores nationwide including tobacco stores, convenience stores, gasoline service stations, grocery stores, and liquor stores. These retail members sell cigarettes and tobacco products and understand the responsibility of selling an age-restricted product to legal age adults.

The FDA Should Not Regulate Premium Cigars Until Litigation is Finalized

The FDA should refrain from drafting any proposed regulations related to premium cigars until all appeals are fully resolved in the federal litigation titled *Cigar Association of America, International Premium Cigar and Pipe Retailers Association, and Cigar Rights of America v. United States Department of Health and Human Services and the United States Food and Drug Administration*, Case No. 1:16-cv-01460. In addition, a broader knowledge of the premium cigar industry would be beneficial for the FDA as the agency contemplates potential regulations and it should consider taking the opportunity to dialogue with members of the premium cigar industry.

The Regulation of Premium Cigars

The FDA is seeking information related to premium cigars and their use, in particular new and

different information and data not submitted in response to the FDA's proposed deeming regulation. In response to the specific information requested by the FDA in the Premium Cigar ANPRM, NATO has conducted a survey of its retail membership and asked such questions as the average age at which individuals began to smoke premium cigars, did individuals start smoking premium cigars before smoking or using other tobacco products, what other tobacco products are used by premium cigar smokers, and the number of premium cigars smoked per day or per week, and per month. A compilation of the survey responses received from NATO members is provided below as new information in response to the Premium Cigar ANPRM.

Average Age at Which Adults Began Smoking Premium Cigars

Survey Question: What is the average age at which your customers started to smoke premium cigars?

Total Number of NATO members responding to the survey question: 46.

<u>Age</u>	<u>Number of Responses</u>
18	1
20	2
22	1
23	2
24	2
25-30	18
30-35	18
40	1
45	1

Did Individuals Start Smoking Premium Cigars Before Using Other Tobacco Products?

Survey Question: Did your customers start smoking premium cigars before smoking or using any other tobacco product?

Total Number of NATO members responding to the survey question: 46.

Yes: 36%

No: 64%

Other Tobacco Products Used by Premium Cigar Smokers

Survey Question: Do premium cigar smokers also use any of the following kinds of tobacco products?

Domestic Cigars: 52%

Cigarettes: 24%

Electronic Cigarettes/Vapor Products: 7%

Pipe Tobacco: 54%

Smokeless Tobacco: 11%

Hookah Tobacco: 0%

Number of Premium Cigars Smoked During Different Time Periods

Survey Question: On average, how many premium cigars do your customers smoke per day?

<u>Number Smoked</u>	<u>Number of Responses</u>
1	17
2	6
3	1
4	1

Survey Question: On average, how many premium cigars do your customers smoke per week?

<u>Number Smoked</u>	<u>Number of Responses</u>
1	1
2	7
3	11
4	6
5	8
6	1
7	2
8	2
10+	3

Survey Question: On average, how many premium cigars do your customers smoke per month?

<u>Number Smoked</u>	<u>Number of Responses</u>
1	1
4	1
6	2
8	1
10-12	9
13-16	3
20-25	9
30+	3

NATO appreciates the opportunity to submit these comments and this survey data in response to the Premium Cigar ANPRM.

Sincerely,

Thomas A. Briant

NATO Executive Director and Legal Counsel