

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

Re: Docket No. FDA-2011-D-0147

Dear Sir or Madam:

Cigar Rights of America (“CRA”) submits these comments in response to the Food and Drug Administration’s (“FDA’s” or the “Agency’s”) request for comments and information regarding the “Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance for Industry and Food and Drug Administrations Staff; Section 905(j) Reports: Demonstrating Substantial Equivalence for Tobacco Products.”¹ Cigar Rights of America represents the Nation’s leading cigar manufacturers of premium hand rolled cigars as well as consumers and retailers of premium cigars counting members in all 50 states.

- A. *Not only is the proposed collection of information for premium cigars unnecessary for the proper performance of FDA's functions but it will divert the agency's limited resources away from other important work*.....
- 1. *Because premium cigars are smoked infrequently and are not used by minors, they are distinct from all other tobacco products*.....

Congress enacted the Tobacco Control Act “to ensure that the Food and Drug Administration has the authority to address issues of particular concern to public health officials, especially the use of tobacco by young people and dependence on tobacco.”² FDA’s own research, however, has found that one of the most critical of Congress’s stated reasons for regulating tobacco products – youth use and addiction – are not present in premium cigars.

First, the Population Assessment of Tobacco and Health (“PATH”) study, administered by the FDA and the National Institutes of Health, has founded that children do not smoke premium cigars. Last year, FDA staff published an analysis of PATH data in the *New England Journal of Medicine* and reported that there is **no statistically significant use of “traditional cigars”³ by persons younger than 18 on a “daily” or “frequent” basis.**⁴ Instead, in an article in *Nicotine and Tobacco Research*, FDA staff explained that the median age of “first regular use” for “premium cigars” is 24.5 years old with a 95% confidence interval of 18.8 years old to 32.6 years old.⁵ Accordingly, FDA’s own staff and research have found that minors are not using premium cigars.

¹ 82 Fed. Reg. 42,501 (Sept. 8, 2017).

² 21 U.S.C. 387 note § 3(2).

³ The category of “traditional cigars” in the PATH study was defined in a way that included *both* handmade cigars and the antique, hand-operated machine-made cigars that J.C. Newman rolls in his historic Tampa cigar factory.

⁴ Kasza, K. et al., “Tobacco-Product Use by Adults and Youths in the United States in 2013 and 2014,” 376 NEW ENGLAND JOURNAL OF MEDICINE 342–353 (Jan. 26, 2017).

⁵ Corey, C., NICOTINE & TOBACCO RESEARCH, at 5.

Second, the National Adult Tobacco Survey, administered by the U.S. Centers for Disease Control and Prevention (“CDC”), found that premium cigars are used infrequently. An article written by FDA staff and published in the CDC’s *Morbidity and Mortality Weekly Report* analyzed 2012–2013 NATS data and found that **96.7% of premium cigar consumers smoke fewer than one premium cigar per day**.⁶ The aforementioned article in *Nicotine & Tobacco Research* on PATH data concluded that the median premium cigar consumer smokes 1.7 cigars per month.⁷ Because the typical consumer smokes fewer than two premium cigars per month, the patterns of use for premium cigars are simply not consistent with addiction.

The fact that premium cigars are smoked infrequently is particularly important because government-funded studies of data spanning decades have concluded that smoking cigars infrequently presents no statistically significant increase in the rate of mortality over non-smokers as the difference is within the study’s margin of error. Earlier this year, FDA staff and other researchers published an article in *JAMA Internal Medicine* that analyzed 25 years of data from the National Longitudinal Mortality Study. They found that there is no statistically significant increase in mortality for adults who smoke less than one cigar per day – just as 97% of premium cigar smokers do.⁸ This research confirmed the analysis published in 1998 by the National Cancer Institute in Monograph No. 9.⁹ The issues of youth access, patterns of use, and health effects of premium cigars are discussed in much greater depth in the comments submitted on behalf of the International Premium Cigar and Pipe Retailers Association and Cigar Rights of America in response to the Advanced Notice of Public Rulemaking on premium cigars last summer.¹⁰

2. *Yet, FDA is requiring voluminous and irrelevant information in substantial equivalency reports for premium cigars.*

Although premium cigars are not used by children and are smoked infrequently, FDA is subjecting premium cigars to the same exhaustive and costly substantial equivalency process developed for cigarettes and all other tobacco products. FDA’s approach is highly problematic for two reasons: (1) premium cigar makers do not have the detailed, scientific information about their products that FDA is requesting, (2) to the extent that such information can be obtained, it is cost prohibitive, particularly since the premium cigar industry is largely comprised of small, family businesses and (3) there is no indication with it would lead to any meaningful benefit to public health.

It is important for FDA to understand that premium cigars are an inherently unscientific product. Unlike other homogenized, machine produced tobacco products; premium

⁶ Corey, C. et al., “Little Filtered Cigar, Cigarillo, and Premium Cigar Smoking Among Adults — United States, 2012–2013,” *MORBIDITY AND MORTALITY WEEKLY REPORT* (Aug. 1, 2014).

⁷ Corey, C., *NICOTINE & TOBACCO RESEARCH*, at 7. This study also concluded that 93.3% of premium cigar consumers smoked less than one cigar per day, slightly lower than the 96.7% reported in 2014.

⁸ Christensen, C. et al., “Association of Cigarette, Cigar, and Pipe Use With Mortality Risk in the US Population,” *JAMA INTERNAL MEDICINE* (Feb. 19, 2018), at E6 (Table 3).

⁹ “Cigars Health Effects and Trends: Smoking and Tobacco Control Monograph No. 9,” NATIONAL CANCER INSTITUTE (1998) at *i*. [FIX]

¹⁰ Comments from the International Premium Cigar and Pipe Retailers Association and Cigar Rights of America (Jul. 25, 2018), <https://www.regulations.gov/document?D=FDA-2017-N-6107-8583>.

cigars are handcrafted using only naturally fermented tobaccos, adhesive, and water. The “technologies” involved in making premium cigars are simply a table, a knife, a cigar mold, and a hand-operated cigar press. Hand rolling premium cigars is an art and a tradition that has been passed down from generation to generation. **Because of this, the scientific data that FDA is requiring for substantial equivalency reports for premium cigars simply do not exist.** Among others, FDA has asked premium cigar manufacturers to include “target specification and upper and lower range limits” in their substantial equivalency reports for each of the following:

- a. Cigar draw resistance (mm H₂O)
- b. Tobacco filler mass (mg)
- c. Tobacco rod density (g/cm³)
- d. Tobacco moisture (%)
- e. Wrapper basis weight (g/m²)
- f. Wrapper porosity (CU)
- g. Wrapper mass (mg)
- h. Binder basis weight (g/m²)
- i. Binder porosity (CU)
- j. Binder mass (mg)¹¹

FDA has said that such information is “needed in order for FDA to make a scientific finding as to whether [] SE Reports establish substantial equivalence.¹²” **However, premium cigar makers do not have this type of detailed information because premium cigars are not made to scientific standards.** They are artisanal, handcrafted products subject to the natural variation of the tobacco leaves themselves and the variation in skill of individual cigar makers who roll each cigar, individually, by hand.

Additionally, **FDA is requiring premium cigar manufacturers to submit detailed HPHC information in their substantial equivalency reports.¹³ However, the agency has yet to provide guidance not only for which HPHCs premium cigar makers need to test but how premium cigars are to be tested.** Although well-established international standards exist for testing cigarettes and other mass-market tobacco products, there are no standards or procedures for testing premium cigars. A principal challenge is that premium cigars come in a myriad of shapes, unlike cigarettes, which have standard sizes. The equipment that would be necessary to undertake such testing for the vast majority of premium cigars is not even available to the laboratories, which conduct these tests for other tobacco products

Inexplicably, not only is FDA requiring voluminous amounts of data on premium cigars in substantial equivalency reports, but the agency is also requesting that premium cigar manufacturers submit detailed scientific information on the decorative cigar boxes, labels, and bands that are used to pack premium cigars as well. The agency has written that substantial equivalency reports for premium cigars should include:

¹¹ [Exhibit A]

¹² Exhibit A at 2.

¹³ Premium cigar manufacturers are also required to file standalone HPHC reports on all of their products by November 8, 2019.

detailed packaging material information, including a detailed ingredient list, for the cellophane, wooden box, and cigar band for all the new products and the wooden box and cigar bands for the predicate product. If any difference exists in any components or ingredients of the packaging (e.g., film, inks, adhesives, label, paper, and wood), provide a side-by-side comparison of the packaging to identify each difference.

What value to the agency and the public does requiring premium cigar makers to undergo the costly and time-consuming process of analyzing the inks printed on a cigar box or a cigar band provide, particularly in light of the fact that changes to the box and labels have been determined NOT to constitute new or different tobacco products by the Federal courts.

Moreover, FDA staff explained this month that environmental assessments required for substantial equivalency reports require detailed environmental analyses of the product's entire supply chain. For premium cigars this would include the farms around the globe where cigar tobacco is grown and the factories where they are made, an analysis of the ash generated when a cigar is smoked, and the portion of the cigar that remains after the consumer finishes smoking it. FDA staff suggested that aerial photos of the farms and factories and analyses of "air quality, water resources, land use and zoning, biological resources, geological features and soils, socioeconomic and environmental justice, solid waste and hazardous waste" and more should be considered in the environmental assessments submitted as part of substantial equivalency reports.

It is conceivable that a premium cigar manufacturer could provide all of the scientific information that FDA is requesting in its substantial equivalency reports. However, the cost of satisfying FDA's requests would be enormous, particularly since the vast majority of premium cigar manufacturers are small, family businesses who hand roll premium cigar in small batches – none of whom employ scientists or regulatory specialists. Premium cigars are just 0.5% of the American tobacco industry – a tiny fraction – and lack the standardization, mechanization, and economies of scale of cigarettes. Given that FDA's own research concluded that premium cigars are not used by minors, are smoked infrequently, and are unscientific products, it makes no sense to subject them to the same cost prohibitive substantial equivalency requirements as cigarettes and other tobacco products. Moreover, the Agency has previously determined that minor variations due to changes in tobacco blends year to year do not trigger additional filings or information requirements. How would information on two different small, family owned farms in, say Nicaragua be meaningful?

3. *Moreover, analyzing premium cigars hand rolled today and comparing them with those hand rolled 12 years ago is inherently unreliable and is unscientific*

Congress created the substantial equivalency pathway to allow new tobacco products to be sold if they were found to be "substantially equivalent" to ones that were on the market as of February 15, 2007.¹⁴ The Tobacco Control Act states that a new product can be deemed "substantially equivalent" and allowed to be sold if FDA has found that the new tobacco product "has the same characteristics as the predicate tobacco product."¹⁵ Congress defined

¹⁴ 21 U.S.C. § 387e (j).

¹⁵ 21 U.S.C. § 387j (a)(3)(A)(i).

“characteristics” to mean “the materials, ingredients, design, composition, heating source, or other features of a tobacco product.”¹⁶

The process outlined by Congress is clear and simple. As explained above, however, FDA’s application of substantial equivalency is very cumbersome, complex, and costly because the FDA is requiring detailed scientific analysis of handmade cigars from today and a comparison with those rolled a dozen years ago. In reality, this process is an expensive artifice that masks several fundamental flaws: First, premium cigar manufacturers generally do not have old cigars that are a dozen years old; because handmade cigars are perishable, premium cigar manufacturers tend to sell them quickly. Second, even if a premium cigar maker does have a premium cigar from 2007, that cigar is different today than it was a dozen years ago. Just like fine wines that age and change over time, premium cigars also evolve over time and their characteristics change.¹⁷ Third, as scientists have found, there is great natural variation in premium cigar tobacco.¹⁸ FDA does allow manufacturers who do not have products from 2007 to try to recreate them, but given how tobacco naturally varies that process further reduces accuracy of the scientific testing required for substantial equivalency reports.

Accordingly, trying to scientifically compare a premium cigar rolled today with one from 2007 is a just a very costly pretense that has very little “practical utility” and is not “necessary for the proper performance of FDA's functions.”

4. *Processing thousands of substantial equivalency reports for premium cigars will consume a grossly disproportionate amount of agency resources that would be more effectively spent elsewhere.....*

In the past few years, FDA has been challenged by a large backlog of tobacco premarket review applications. With the deadline for newly deemed products to submit premarket review applications swiftly approaching, the agency’s workload is about to significantly increase. In total, the premium cigar industry expects that thousands of substantial equivalency reports will need to be filed for premium cigars.

As described above, substantial equivalency reports are massive, exhaustive, and costly documents that require not only enormous amounts of time for applicants to prepare but also

¹⁶ *Id.* at (a)(3)(B).

¹⁷ Premium cigars are a natural product subject to significant natural variation. Just as the soil, sunlight, wind, and rain cause a Merlot grape grown in France to taste different from the same Merlot grape grown in California, the same is true of premium cigar tobacco. As with wines, certain vintages or years are known to be better than others; the same is true with premium cigar tobacco. And just as aging red wines makes them better, the same is true for premium cigars as well. Like old world French winemakers who blend together different grape varieties to create unique tasting wines, as cigar makers, we do the exact same thing with premium cigar tobacco. We harness the natural variation in premium cigar tobaccos to make interesting blends with limited production, low-volume runs, just like winemakers do with grapes.

¹⁸ Science supports this. The authors tested the same brands of large cigars in 2015 and in 2016. They found that “in the two large cigar and cigarillo brands analyzed a second time, there was considerable within-brand variance in nicotine content and concentration between the first and second analyses.” The “percent free nicotine differed by 16%-45%” between the years “[d]espite consistency in physical properties,” such as size and weight. Bartosz Koszowski et al., *Nicotine Content and Physical Properties of Large Cigars and Cigarillos in the United States*, NICOTINE & TOBACCO RESEARCH, at 3 (Mar. 1, 2017).

substantial amounts of time for the agency to process. FDA will have to dedicate tremendous agency resources to review the thousands of substantial equivalency reports for premium cigars. Given that premium cigars comprise just 0.5% of the tobacco industry, are not used by children, and are smoked infrequently, it does not make sense for FDA to devote a massive amount of agency resources to substantial equivalency reports for premium cigars – particularly when those resources could much better be used to further FDA’s ambitious regulatory agenda.

B. *FDA has substantially underestimated the burden of the proposed collection of information for premium cigars.....*

1. *The requirements for substantial equivalency reports for premium cigars are exhaustive.....*

FDA has estimated that it expects to receive just 683 standalone substantial equivalency reports and 456 bundled reports per year, and that it will take each applicant 300 hours to prepare each standalone report and 90 hours to prepare each bundled report. These numbers are very low.

The agency goes on to project the annual average of 979 SE’s will increase to 1,570. There are estimated to be 20,000 separate premium cigar products (as defined by Stock Keeping Units ((SKU’s)) on the market today. It has been estimated that 60 percent of SKUs will not be grandfathered (At 12,000 SKUs, the agency would be inundated.) 15-20% of the market turns over each year due to new products, limited editions, etc., thus upwards of 2400 products per year can be expected. This figure is well above the estimated 1,570 reflected in the Federal Register figure (Vol. 83, No. 173/Thursday, September 6 Docket No. FDA-2011-D-0147).

FDA estimated the “costs” for completing the applications above in hours, rather than in dollar figures. That’s because FDA is basing its assumptions on extrapolation from their experience regulating large cigarette companies. Those large companies have in-house teams of regulatory compliance specialists and scientists who complete these applications; thus, their primary cost is time. Clearly, the economics of the premium cigar industry are quite different. Cigar manufacturers typically do not have in-house teams of scientists to conduct testing on harmful and potentially harmful constituents (HPHCs) and will, at minimum, be expected to contract that work out to independent labs. FDA’s narrow interpretation of the criteria for an SE exemption means that essentially all new cigar products will be required to file a full SE report. The costs for the HPHC testing along with the legal fees required for those reports, is likely to be a minimum of \$20,000 to upwards of \$50,000 per product. This makes it very difficult for the typical small, family-owned cigar company to absorb those costs.

First, the premium cigar industry expects to submit thousands of substantial equivalency reports for premium cigars prior to the August 8, 2021 deadline. This will be in addition to all of the other applications filed by manufacturers of other newly deemed products.

Second, FDA estimated that each respondent would submit only a single application per year. One of our mid-sized manufacturers expects to submit 166 substantial equivalency reports for premium cigars alone, and another mid-sized brand owner estimates that it alone anticipates the need to file approximately 300 substantial equivalency reports for review.

Third, the agency’s estimate of 300 per hours per substantial equivalency application seems quite low given the volume of information that FDA is requesting and the estimates provided by outside consultants. This number also does not account for the costs of the required HPHC testing and the detailed environmental analyses needed for the environmental assessment. Instead, given the information presently available, stakeholders expect that it will take upwards of 1,000 hours to prepare a substantial equivalency report for premium cigars.

2. *Unlike other segments of the tobacco industry, the premium cigar industry is largely comprised of small, family business that lacks the resources to prepare substantial equivalency reports.*

It is important for FDA to remember that premium cigars are just 0.5% of the tobacco industry and are comprised of many small, family-owned businesses. Because premium cigars are made without modern technology, startup costs in our industry are extremely low. Accordingly, our industry is filled with many small manufacturers. Unlike other parts of the tobacco industry that have massive market shares and in-house scientists, regulatory experts, and laboratories, premium cigar manufacturers lack these internal resources. Therefore, preparing substantial equivalency reports will take much longer and be more difficult for premium cigar manufacturers than other larger tobacco manufacturers.

3. *The labs that we’ve spoken with confirm that an entirely new set of tolerance standards and testing methodologies would be required to gather meaningful data on premium cigars – the old methods could not simply be adapted for this new purpose.*

Furthermore, the labs we queried indicate that, even if new testing standards were developed, premium cigars might be too variable in nature for them to provide meaningful data. Whereas cigarettes and mass-market cigars are carefully controlled products designed to prevent any variation from one experience to the next, premium cigars are a handcrafted, agricultural product. Scientists we have spoken with believe that the variability of premiums is great enough that they do not believe that testing could distinguish one brand from another and that the information would provide little of use to FDA. (The CORESTA workgroup has found that production and product related reasons as well as the lower number of cigars smoked per result and the smoking technology available make it impossible to reach the same reproducibility levels obtained for cigarettes”). Moreover, they found “due to the wide range of products, cigars cannot be smoked in a fully automated manner. And more importantly the high cigar variability is mainly caused by reasons related to the cigar production system and to the inherent characteristics of the product itself.”

- C. *Accordingly, as supported by the science and for an efficient use of limited agency resources, the FDA should exempt premium cigars from FDA regulation, including substantial equivalency.....*

Subjecting premium cigars to the same rigorous and costly substantial equivalency process developed for cigarettes and mass-market tobacco products is not necessary for the FDA to achieve its goals – particularly since FDA’s research has found that children are not using

premium cigars, premium cigars are smoked infrequently and when smoked infrequently, there is no statistically significant increase in mortality outside the assigned margin or error. Premium cigars are distinct, handcrafted products made by small family businesses that lack the expertise and capacity of large tobacco companies to prepare these reports. Processing all of the substantial equivalency reports for premium cigars will take a grossly disproportionate amount of limited agency resources, diverting it from the agency's other regulatory priorities. **Therefore, FDA should exempt premium cigars from FDA regulation, including the substantial equivalency process.**

Sincerely,

Michael Copperman

Michael Copperman
Director of Federal Regulatory & Legislative Affairs,
Cigar Rights of America