MEMORANDUM

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| To: | Office of Management and Budget/ Office of Information and Regulatory Affairs |
| Date: | December 19, 2016 |
| RE: | RIN 0910-AG96 |

On November 16, 2016, representatives from various cigar industry stakeholders met with staff from OMB/OIRA and FDA regarding a proposed rule, entitled “Format and Content of Reports Intended to Demonstrate Substantial Equivalence,” currently under review at OMB/OIRA. At the conclusion of this meeting, we requested and were granted permission to file a post-meeting submission.

During the meeting, we (i) outlined concerns regarding FDA’s position on demonstrating substantial equivalence, specifically with respect to cigars, and (ii) offered suggestions on how substantial equivalence should be determined for cigars, consistent with congressional intent, the Tobacco Control Act, and related guidance.

By way of background, we discussed the unique nature of cigars and the cigar industry, specifically (i) that cigars are a small part of the overall tobacco market (FY17 cigar industry user fees are 9.7% of the total, with “premium” cigars being a fraction of 1%); (ii) that the industry is made up of many small manufacturers and importers (113 domestic manufacturers and 216 importers, by FDA’s count based on TTB data); (iii) that despite its small relative size, the cigar industry has at least ten times the number of SKUs as cigarettes, with over 10,000 cigar SKUs having been introduced in just the three months between publication of the Final Rule on May 10, 2016 and the August 8, 2016 effective date; and (iv) that often the same cigar comes in a wide variety of sizes, shapes, and packaging configurations.  We reiterated our concern over the nine year “look back” period for cigars to get to predicate products, and the resultant fact that all cigars commercially marketed after February 15, 2007 will be required to go through pre-market review, while initially regulated products have a two year “look back” period.  We also pointed out that the Tobacco Control Act clearly demonstrates congressional intent that different tobacco products be regulated differently, taking into account (among other factors) the relative resources of segment stakeholders, practical considerations, and relative health risks of various products.

Specifically, with respect to substantial equivalence reports (“SEs”), we believe as an overarching principle that SEs should be tailored to specific classes of products, consistent with FDA’s mandate to review SEs based on what is appropriate for the protection of the public health.  We listed several specific concerns regarding the current SE structure.

**First,** cigars do not have the protection afforded other segments of the tobacco industry that were allowed to file provisional SEs; as long as these provisional SEs were timely filed, the products at issue were formally allowed to remain on the market until the SEs were decided.  For cigars, there is no such compliance policy; rather cigars with pending SEs are subject to enforcement if the SE is not decided within 12 months.

**Second,** as a result of FDA’s decision to use the same predicate date for all products, there will be an enormous number of SEs for cigars, far exceeding the number filed for initially regulated products.  Based on the time needed to process SEs thus far (with some pending for a number of years), we question FDA’s ability to process these cigar SEs within the 12 month compliance period.

**Third,** most cigar manufacturers no longer have actual cigars manufactured in 2007, which are to be used as predicates.  This presents obstacles to providing the types of information on predicate products that FDA is currently requesting.

**Fourth,** given the product testing FDA will apparently require (based on SEs for initially regulated products), the costs of such testing will be prohibitive.  Cigar companies should not and cannot be forced to choose which cigars they want to attempt to keep on the market based on a financial ability to have testing done.

**Fifth,** with respect to any cigar constituent testing, while FDA indicated it will accept the CORESTA methodology, many questions still exist about the application and use of this methodology; therefore, cigar companies do not know what to test for, or precisely how labs are to test for it.

**Sixth,** there are a limited number of labs that are certified to do constituent testing.  Given the anticipated volume of SE submissions and the number of SKUs that may have to be tested, we have concerns about lab capacity and ability to complete the necessary testing within the timeframe established by FDA.

We then made several suggestions regarding SEs for cigars that comply with FDA’s mandate, recognize differences between and among products, and address the concerns raised above.

**First,** any rule or guidance on SEs for cigars must be specific as to what should be included.  In considering provisional SEs for cigarettes and smokeless tobacco products, FDA often requested additional information, frequently going beyond that contained in the statute or guidance.  Manufacturers submitting SEs for cigars need to know that if the specified information is provided, the SE will be considered complete and appropriate for review.  This is particularly critical given the 12 month compliance period discussed above.

**Second,** manufacturers should provide certain objective information in the SE – this could include (i) the type, variety, and cure method of the tobaccos used in the cigar; (ii) the weight of the finished product; (iii) the size of the cigar (by length and ring gauge); and (iv) a list of ingredients (including any additives).

**Third,** FDA should recognize that different testing requirements should apply to different types of cigars; for example, those with and without additives.  If testing of cigars is required, a baseline might include testing for tar, nicotine, carbon monoxide (TNCO).

**Fourth,** should constituent testing be required for cigar SEs, we suggest the agency engage in discussion with industry and certified labs to ensure both that industry knows what testing protocols and regimes to use, and that testing results will be meaningful and acceptable to FDA.

**Fifth**, FDA has recognized that cigars are subject to blending changes that result from “natural variations” in tobacco. The agency concluded that “blending changes required to address the natural variation of tobacco (e.g. blending changes due to variation in growing conditions) in order to maintain a consistent product” do not create a new product requiring FDA premarket review.  We believe FDA should set ranges for “natural variations” and recognize that from a testing perspective results for two cigars falling within these ranges are presumptive evidence of substantial equivalence.

**Sixth,** quantity changes are important for the cigar industry; the same cigar is often introduced in different pack sizes.  FDA’s current guidance requires manufacturers to provide “scientific data demonstrating that a change in product quantity is not likely to alter consumer use behavior” between the predicate and the new product. There is no apparent basis to believe that the same cigar in different pack sizes alters consumer use behaviors. We suggested therefore that quantity changes for cigars not be required to provide scientific data on consumer use behavior.