CRA

CIGAR RIGHTS OF AMERICA

FIGHTING FOR THE FREEDOM TO ENJOY PREMIUM CIGARS

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Submitted via www.regulations.gov
Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: FDA Docket No. FDA-2012-N-0920, Proposed Rule Requiring Domestic Tobacco Product Manufacturers and Importers to Submit Information to Calculate User Fees

To Whom It May Concern:

I am writing on behalf of Cigar Rights of America ("CRA") to comment on the Food and Drug Administration's ("FDA") proposed rule requiring domestic tobacco product manufacturers and importers to submit to FDA information needed to calculate the amount of user fees assessed under the Federal Food, Drug and Cosmetic Act (the "FD&C Act"). CRA is a national advocacy organization dedicated to protecting the rights of consumers, retail tobacconists, suppliers and manufacturers of premium cigars.

The purpose of our comments is to request that FDA modify the proposed rule as outlined below. As a threshold matter, we believe that it is inappropriate for FDA to impose user fees on premium cigars because premium cigars should not be regulated by FDA. CRA also believes that, in the event that the final rule imposes user fees on cigars, the allocation method should be changed.

Section 919(a) of the FD&C Act provides that FDA shall "assess user fees on, and collect such fees from, each domestic manufacturer and importer of tobacco products subject to" the FD&C Act's tobacco product provisions. 21 U.S.C. § 387s(a). The FD&C Act provides that the total assessment of the user fees shall be divided among the six classes of tobacco products set forth in the statute: (1) cigarettes; (2) cigars; (3) snuff; (4) chewing tobacco; (5) pipe tobacco; and (6) roll-your-own tobacco. *Id.* § 387s(b)(2)(B)(i). The proposed rule makes clear that domestic manufacturers and importers of the two classes that are not currently subject to FDA regulation (cigars and pipe tobacco) are not required to pay user fees unless they are deemed subject to FDA's jurisdiction. The proposed rule indicates that cigars will be subject to user fees if and when FDA begins to regulate cigars. To date, FDA has not issued a proposed rule subjecting cigars to FDA authority.

FDA Should Not Regulate Premium Cigars

CRA objects to the proposed rule's extension of user fees to cigars because premium cigars should not be regulated by FDA. Premium cigars are different from other tobacco products currently subject to FDA regulation, a distinction that FDA has previously recognized. In 1996, when FDA first issued a rule asserting regulatory authority over cigarettes and smokeless tobacco, cigars were expressly exempted. In rejecting comments that urged FDA to regulate cigars, FDA stated that "there is insufficient evidence of cigar or pipe tobacco use by children and adolescents to support the inclusion of cigar[s] . . . within the scope of the final rule." Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents, 61 Fed. Reg. 44369, 44421-22 (Aug. 28, 1996). Nothing has changed since then. There is still no evidence that minors use premium cigars in significant quantities. In fact, as recently as July 2012, the House Appropriations Committee reminded FDA that "premium cigars have unique characteristics and cost-prohibitive price points and are not marketed to kids" and that "[a]ny effort to regulate cigars should take these items into consideration." H.R. Rep. No. 112-542, at 46 (2012).

More recently, Congress has signaled its intent that FDA should not regulate premium cigars. On February 15, 2013, the U.S. House of Representatives introduced a bill that proposes to amend the FD&C Act to remove premium cigars from FDA's jurisdiction. H.R. 792 (2013). The bill already has 116 cosponsors. On April 18, 2013, the U.S. Senate introduced Senate Bill 772 as a companion bill to House Bill 792. S. 772 (2013). The Senate bill already has 10 cosponsors. The 2012 versions of these bills respectively had 220 (a majority of the House) and 13 cosponsors. If either bill passes, cigars that meet the definition of a "premium cigar" will not be subject to FDA regulation. Generally, the bills define a "premium cigar" as a roll of tobacco weighing at least 6 pounds per 1,000 count that is wrapped wholly in leaf tobacco and bunched with 100% tobacco filler; does not contain a filter, tip or non-tobacco mouthpiece; is made by hand and has 100% leaf tobacco binder, or is made only using human hands to lay the wrapper onto only one machine; and is not a cigarette or little cigar by definition.

Exempting premium cigars from FDA regulation is consistent with premium cigar consumer age demographics, and premium cigar consumer usage and inhalation patterns. As noted above, there is no evidence that minors use premium cigars in any significant quantities. Moreover, the vast majority of premium cigar consumers are only occasional users (one cigar per day or less), and an occasional smoker by definition cannot be addicted. In fact, Monograph 9 emphasizes the fact that few people are "regular" cigar smokers. As stated in Monograph 9: "Most cigarette smokers smoke every day. In contrast, as many as three-quarters of cigar smokers smoke only occasionally, and some may only smoke a few cigars per year." National Cancer Institute (1998). Smoking and Tobacco Control Monograph 9: Cigars: Health Effects and Trends. The 2010 Surgeon General's Report *How Tobacco Smoke Causes Disease* also makes this point. That report states: "Most current cigar users are young males who often smoke less than one cigar daily."

Further, there is no evidence that occasional premium cigar smokers are at increased risk of mortality or morbidity. (Iribarren, C., et al., 1999. Effect of cigar smoking on the risk of cardiovascular disease, chronic obstructive pulmonary disease, and cancer in men. New England Journal of Medicine. 340, 1773-1780). Cigars deliver very little nicotine, largely because the

smoke is not inhaled or absorbed in the buccal cavity. The major metabolite of nicotine (cotinine) was measured in two recent studies (Rodriguez, J., et al., The association of pipe and cigar use with cotinine levels, lung function, and airflow obstruction: a cross-sectional study. Annals of Internal Medicine, 2010. 152(4): p. 201-10; Funck-Brentano, C., et al., Effects of type of smoking (pipe, cigars or cigarettes) on biological indices of tobacco exposure and toxicity. Lung Cancer, 2006. 54(1): p. 11-18). The results from these studies confirm that nicotine absorption (by either the inhalation or oral route) is effectively absent in cigar smokers. Hence, these cigar smokers cannot be nicotine-dependent, assuming that the nicotine titration theory is correct (McMorrow, M. J., Foxx, R. M., 1983. Nicotine's role in smoking: an analysis of nicotine regulation. Psychological Bulletin. 93, 302-27). Occasional cigar smokers are at no increased risk of any cancers, and specifically lung cancer (Monograph 9 at Chapter 4, Table 7), buccal and pharyngeal cancer (Monograph 9 at Chapter 4, Table 11), cancer of the larynx (Monograph 9 at Chapter 4, Table 18), and cancer of the esophagus (Monograph 9 at Chapter 4, Table 21). FDA's regulatory policy must account for the fact that premium cigars smokers have far different usage patterns and health impacts than cigarette smokers.

Second, applying the FD&C Act to premium cigars raises fundamental fairness concerns. This is best exemplified by the fact that a literal application of FDA's new tobacco product authority to premium cigars could prohibit the sale of new or altered products, which would constitute an impermissible ban on premium cigars. Section 910 of the Tobacco Control Act defines a "new tobacco product" as one that was not commercially marketed in the United States as of February 15, 2007, or that has been changed *in any way* since February 15, 2007. 21 U.S.C. 387j(a)(2)(A). Generally, new tobacco products cannot be commercially marketed without an order from FDA.

If applied literally, any premium cigar introduced or changed since February 2007 cannot be sold without FDA approval unless the cigar was sold prior to March 2011 and the manufacturer submitted the required substantial equivalence report prior to March 2011. Premium cigar manufacturers did not submit those reports by the March 2011 deadline because cigars were not subject to FDA's authority at that time. Under this application of the new tobacco product requirements, all cigars first commercially marketed or changed after February 2007 would have to be removed from the market until FDA has approved the product. This would be tantamount to a ban on cigars, which is unlawful under the Tobacco Control Act.

Moreover, application of the new tobacco product requirements to premium cigars will present financial challenges for cigar manufacturers not faced by other tobacco product manufacturers. While cigarettes are homogenous and consistent products, hand-made premium cigars are "small batch" products. There are often minor variations intended to alter the taste or aroma of the new product, including using tobaccos from different regions or seed varieties to create different taste profiles. Such variations would trigger a time-consuming and expensive review process, without any discernible impact on public health. Even brands that have been on the market before February 2007 would be considered new products because of various changes to the products' composition, as premium cigar manufacturers seek to maintain consistency in product quality, taste, etc. in the face of sometimes significant changes in the climate, soil, etc. from one year to the next.

New tobacco product requirements would be disproportionately expensive for premium cigar manufacturers because they generally offer a large variety of products with slight variations. It would also substantially increase FDA's already substantial workload in evaluating these applications. The typical premium cigar manufacturer may have over 100 unique stock-keeping units ("SKUs"), and typically will turn-over about 15% of those SKUs in any given year, each of which would trigger new tobacco product requirements. Public data indicates there are at least 1,400 premium cigar brands in the United States, which would add to FDA's already-overwhelming workload in evaluating new product applications. If FDA has only been able to evaluate six applications out of the more than 3,500 applications it has received since March 2011, how could FDA possibly accommodate the workload generated by thousands of additional new product applications from the premium cigar industry?

The new product requirements are just one example of how FDA regulation would be disproportionately burdensome for the premium cigar industry. Other examples include testing requirements, tobacco product standards (including potential nicotine level limitations), good manufacturing practice requirements and remote sales limitations. These burdens, coupled with the negligible public health benefits discussed above, make it appropriate to exempt premium cigars from FDA regulation. Such an exemption could be mandated by Congress, or FDA could exempt premium cigars through its own initiative. Assuming that premium cigars are properly exempted from FDA jurisdiction, it would be inappropriate to impose user fees on these products.

The User Fee Methodology is Flawed

Even if FDA regulates premium cigars, the proposed rule's allocation of user fees to cigar manufacturers and importers is flawed. Under the proposed rule, FDA plans to use the United States Department of Agriculture's ("USDA") methodology to determine the amount of assessments levied upon tobacco product manufacturers and importers under the Fair and Equitable Tobacco Reform Act ("FETRA").

Under FETRA, Congress adopted a two-step process for the USDA to determine assessments owed by tobacco product manufacturers and importers. Step A of the process allocates assessments among six classes of tobacco products: (1) cigarettes; (2) cigars; (3) snuff; (4) chewing tobacco; (5) pipe tobacco; and (6) roll-your-own tobacco. Step B then allocates the assessments on a pro-rata basis among the manufacturers and importers within each of the six classes of tobacco products. FDA's proposed rule is modeled on this two-step process.[1]

[1] CRA concurs with the proposed rule's methodology under Step B. To determine the dollar amount that each domestic manufacturer is responsible for within a particular class, Step B uses actual federal excise taxes paid. The actual amount of federal excise taxes paid per manufacturer is divided by the actual total amount of federal excise taxes paid per class. This calculation is done on a quarterly basis. The fact that FDA intends to use actual federal excise taxes for Step B is evidence that FDA possesses the data needed to calculate Step A consistent with CRA's proposal; that is, by using actual federal excise taxes paid rather than the maximum rate from 2003 when calculating the dollar figure per class.

Step A is intended to allocate the assessments among the six classes of tobacco products based on each class's current share of the overall market. Under the proposed rule, FDA intends to calculate a particular tobacco class's overall market share by employing a two-step process.

First, FDA intends to multiply the volume of taxable tobacco units ("volume") per class by the maximum 2003 federal excise tax rate ("2003 maximum rate") per class. Multiplying the volume per class by the 2003 maximum rate per class yields the dollar figure for each class. To account for the differences in excise tax rates for small and large cigars, the volume of small cigars would be multiplied by the 2003 maximum rate for small cigars and the volume of large cigars would be multiplied by the 2003 maximum rate for large cigars. Based on this calculation, the volume per class may vary year to year, but the maximum rate per class is always based on 2003 federal excise tax figures and remains the same. Below is a chart that shows how the first portion of Step A or the dollar figure for each class is calculated under FDA's proposed rule (figures are for illustrative purposes only).

	Volume Per Class x	**2003 Maximum FET =**	**Dollar Figure Per Class**
Cigarettes	300	$5	$1,500
Cigars	100	$5	$500
Snuff	100	$5	$500
Chewing Tobacco	100	$5	$500
Pipe Tobacco	100	$5	$500
Roll-Your-Own	100	$5	$500

Second, FDA intends to use the dollar figures for each class as determined in the first portion of Step A to determine the percentages attributable to each class of tobacco products. To obtain the percentages, FDA will divide the total dollar figure per class by the aggregate dollar figure for all classes. Using the same statistics from the chart above, the following chart shows how the second portion of the Step A or the percentage attributable to each class of tobacco products is calculated under FDA's proposed rule (figures are for illustrative purposes only).

	Dollar Figure Per Class ÷	**Total Dollar Figure for Each Class**	**Percent Per Class**
Cigarettes	$1,500	$4,000	37.5%
Cigars	$500	$4,000	12.5%
Snuff	$500	$4,000	12.5%
Chewing Tobacco	$500	$4,000	12.5%
Pipe Tobacco	$500	$4,000	12.5%
Roll-Your-Own	$500	$4,000	12.5%

This methodology is flawed because it does not accurately account for each class's overall market share. FDA's methodology assumes that all units of product per class are sold at price point that would trigger the 2003 maximum federal excise tax rate for that class. Rather, FDA should multiply the volume per class by the actual federal excise taxes paid for the current year to obtain the dollar figure per class for the first portion of Step A. The dollar figure per class should then be divided by the aggregate dollar figure for all classes.

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In sum, and for the reasons discussed above, FDA should not regulate premium cigars. The proposed rule should account for a regulatory exemption for premium cigars by adjusting the user fee calculation accordingly. Alternatively, and in the event that premium cigars are subject to FDA's regulatory authority, the proposed rule should also use actual federal excise taxes paid for the first portion of the Step A analysis when calculating the dollar figure for each class of tobacco products.

Sincerely,

Mike Copperman
Legislative Director
Cigar Rights of America