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August 7, 2014

VIA ELECTRONIC FILING

Division of Dockets Management (HFA 305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, Maryland 20852

Re: Docket No. FDA-2014-N-0189

Dear Sir or Madam:

The International Premium Cigar & Pipe Retailers Association ("IPCPR") submits these comments in response to the Food and Drug Administration's ("FDA's") proposed rule: Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, As Amended by the Family Smoking Prevention and Tobacco Control Act; Regulations on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products, 79 Fed. Reg. 23,142 (Apr. 25, 2014) (the "proposed deeming regulation"). IPCPR, based in Columbus, Georgia, is a not-for-profit trade group representing premium cigar and tobacco retail shops located throughout the United States and abroad. IPCPR, formerly the Retail Tobacco Dealers of America, was established in 1933. Its 1,700 retail members are small businesses, typically family-owned and operated. IPCPR members operate more than 2,000 retail stores, employ more than 8,000 people, and sell tobacco products, primarily premium cigars, in face-to-face sales, to adults. IPCPR also has a direct economic relationship with more than 350 manufacturers, distributors, and service providers, who employ 7,000 more people, who supply our retail members.

I. Comment on Whether All Cigars Should Be Subject to Deeming Provisions and Which Provisions of the Proposed Rule May Be Appropriate or Not Appropriate for Different Kinds of Cigars

IPCPR strongly opposes Option 1, and supports a slightly modified Option 2 taking into account our comments presented here. As explained in more detail in IPCPR's Citizen Petition (FDA-2011-P-0623), the scientific research demonstrates that the typical premium cigar consumer (1-2 cigars per day or less) is exposed to significantly lower health risks compared to cigarettes both quantitatively and qualitatively. Furthermore, as explained in the IPCPR Citizen Petition, premium cigars are not used to a significant extent by adolescents. Only Option 2 acknowledges these differences between premium cigars and all other tobacco products, and proposes to regulate premium cigars differently. Because premium cigars pose lower health risks than cigarettes and lack significant youth access, FDA's resources are better spent on regulating tobacco products that present more significant public health problems.

II. Comment on Whether the Proposed Definition of "Covered Cigar" is Appropriate to Capture Those Products That, Because of How They Are Used, May Have Less of a Public Health Impact Than Other Types of Cigars, Including Long Filler Tobacco Content, $10 Price Point, and Weight Restrictions as Proposed Elements

Under Option 2 of the proposed rule, FDA proposes to regulate "covered cigars." FDA then "carves out" from the regulations an exemption for certain cigars that have specific characteristics. It is this "carved out" class of cigars that FDA refers to as "premium cigars." The definition of a "covered cigar" is of critical importance to FDA, manufacturers, importers, distributors, retailers, and consumers. FDA investigators (and/or their state counterparts), as law enforcement agents, must be able to determine whether a cigar is a "covered cigar" subject to greater regulatory restrictions, and which cigars are exempt as "premium cigars." Manufacturers control the process of manufacturing the cigar and the different types of tobacco leaf used in the production of these products. Thus, manufacturers have the greatest ability to determine whether a product meets the proposed exclusionary criteria when it leaves the factory. Retailers are largely dependent on the representations made by manufacturers, but are ultimately responsible for how the product is sold, including the retail price. However, both retailers and manufacturers (as well as distributors and importers) bear potential legal liability if a "covered cigar" is improperly sold as a "premium cigar."

Each element of FDA's proposed definition of a "covered cigar" is presented below in bold font. IPCPR provides comments for each element of the definition.

Covered cigar means any cigar, as defined in this part, except a cigar that:

(1) Is wrapped in whole tobacco leaf;

IPCPR supports this element. This concept was proposed as part of IPCPR's definition of a premium cigar in the IPCPR 2011 Citizen Petition (although the exact wording used in the aforementioned document was "wrapped in leaf tobacco"). IPCPR's phrase was taken verbatim from the definition of a "cigar" at 26 U.S.C. § 5702(a) (Internal Revenue Code) and the definition of "little cigar" at 15 U.S.C. § 1332(7) (Federal Cigarette Labeling and Advertising Act). Like FDA's proposed definition, it specifically excludes products with a homogenized tobacco wrapper. A leaf tobacco wrapper is easily visualized, and does not require sophisticated analysis. Thus, FDA and other government inspectors, retailers, importers, distributors, and consumers can identify the type of product at issue.

(2) Contains a 100 percent leaf tobacco binder;

IPCPR supports this element. Like the proposed whole leaf wrapper, a requirement for a leaf tobacco binder would exclude products with a homogenized tobacco binder. Although a binder is not as easily visualized as a wrapper, it could potentially help FDA and other government inspectors, retailers, importers, distributors, and consumers to identify the type of product at issue.

(3) Contains primarily long filler tobacco;

IPCPR supports this element. However, FDA should be aware of several issues that may affect the regulatory utility of this element. "Long filler" is a term used in the industry to describe a cigar filled with predominately whole tobacco leaves that run the length of a cigar. Most premium cigars use only long filler tobacco. However, several factors make it difficult to regulate cigars on the basis of filler type. First, when a torcedore makes a cigar, sometimes he or she will break a piece of the long filler to make an adjustment. The breaking process means that some portion of the cigar filler will not be composed of

whole tobacco leaves. Second, as noted in the proposed regulation, it is difficult to quantify "primarily," and the proposed deeming regulation does not provide such a definition.

Long filler tobacco is not easily visualized. To determine filler content the cigar must be disassembled, which will likely break some of the filler tobacco leaves. Ultimately, there is no simple, reliable test to determine whether a cigar is "primarily long filler," which could be problematic for FDA inspectors, retailers, and consumers.

Unreliable testing combined with a vague requirement that the product must be "primarily" long filler allows IPCPR to conclude that both compliance and enforcement of this element will be difficult. If this becomes an element of the definition of a "premium cigar," a retailer must be able to rely on a manufacturer's representation (e.g., through appropriate labeling, as discussed in section III.B. below) that the product "contains primarily long filler."

(4) Is made by combining manually the wrapper, filler, and binder;

IPCPR supports this element. Most of IPCPR's retail members are experienced tobacconists who can readily determine whether a product is "hand rolled" (or, "combined manually"). Less experienced retailers, however, may not be able to determine whether a cigar is "made by combining manually the wrapper, filler, and binder," particularly if a manufacturer represents that it is. Because manufacturers have control over the manufacturing process, a retailer must be able to rely on a manufacturer's representation (e.g., through appropriate labeling, as discussed in section III.B. below) that the components of the cigar were manually combined.

(5) Has no filter, tip, or non-tobacco mouthpiece and is capped by hand;

IPCPR supports this element. The presence of a filter, tip, or non-tobacco mouthpiece is easily visualized, and does not require sophisticated analysis. Thus, FDA and other government inspectors, retailers, importers, distributors, and consumers can more readily determine the type of product at issue. However, although premium cigars are currently "capped by hand," that feature may not be immediately obvious to an untrained eye. This could lead to both enforcement and compliance issues, and FDA should consider that issue moving forward. A retailer must be able to rely on a manufacturer's representation (e.g., through appropriate labeling, as discussed in section III.B. below) that the cigar was "capped by hand."

(6) Has a retail price (after any discounts or coupons) of no less than $10 per cigar (adjusted, as necessary, every 2 years, effective July 1st, to account for any increases in the price of tobacco products since the last price adjustment);

IPCPR opposes this element. There are several problems with including an explicit cost in the definition of a "covered cigar." The chief difficulty is that retail cost is controlled primarily by retailers. For example, if a retailer sells a cigar for less than $10 that the manufacturer intended to be "premium," would the manufacturer have then made a "covered cigar?" This could expose the manufacturer to legal liability. A second difficulty is that sales tax rates and "other tobacco product" ("OTP") or excise tax rates vary greatly between states. Those excise taxes range from three to 40.5 cents per ten cigars (Alabama) to nothing (Florida) to ten percent of the manufacturer's price (Missouri) to 75 percent of the wholesale price (New York) to 95 percent of the wholesale price with a $3.50 tax cap (Minnesota). These variances, both in amount and in the timing of the assessment, affect the retail price of a cigar, resulting in a great variance in retail price between states for the same cigar. In addition, retail price of all goods is affected by geography, since retail prices tend to be higher in large cities than in rural areas. Thus, some cigars will be designated based solely on where they are sold. IPCPR is not aware of a specific retail

price being an element of regulation by FDA of any other product, even cigarettes, and FDA has not explained why it is appropriate to target premium cigars.

Finally, the Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776 (2009)("Tobacco Control Act"), includes this restriction on retailer records: "The Secretary shall not require any retailer to maintain records relating to individual purchasers of tobacco products for personal consumption." 21 U.S.C. § 387t(b)(5). It is not clear how FDA would enforce a retail price element given this apparently general prohibition.

(7) Does not have a characterizing flavor other than tobacco;

IPCPR accepts this element in principal, but notes that "characterizing flavor" has not been defined in the context of tobacco products, and is not defined in the proposed deeming regulation. To the extent that FDA wants to propose a definition of "characterizing flavor" through future notice and comment rulemaking, which is the appropriate venue for such a discussion, IPCPR looks forward to providing comments through that process. For example, using the precedent set by FDA's food regulations (*see* 21 C.F.R. § 101.22(i)), unless a tobacco product claims to have a characterizing flavor in labeling or advertising, the mere presence of flavoring ingredients should not affect the regulation of the product.

(8) Weighs more than 6 pounds per 1000 units.

IPCPR believes that it is appropriate to use "weight" as a definitional component of cigars, as this has already been established for purposes of taxation.[1] Furthermore, it should be noted that the proposed definition is double the weight necessary to qualify as a "large cigar" for purposes of taxation, further limiting the class. The weight of a cigar is readily determined, which will help FDA and other government inspectors, retailers, importers, distributors, and consumers to more easily determine the type of product at issue.

III. Additional Comments Regarding FDA's Proposed Definition of "Covered Cigar"

A. FDA Should Consider Simplifying and Reducing the Number of Elements That Would Qualify a Cigar as an Exempt "Premium" Cigar

IPCPR shares FDA's concerns that "any attempts to create a subset of premium cigars that are excluded from regulatory authority might sweep other cigar products under its umbrella." 79 Fed. Reg. at 23,150. However, FDA should share IPCPR's concerns that unnecessary overregulation of premium cigars will also have a devastating effect on manufacturers and retailers, particularly small businesses. Given that FDA has no experience enforcing and industry has no experience complying with such regulations, IPCPR believes that it is most appropriate to begin with simple, easy to understand regulations, including the elements of the "covered cigar" definition. This approach will allow FDA and industry to gain both experience and additional information on the effects of regulation. If the initial "umbrella" is later deemed to be too large, FDA can always amend the regulations to capture the products for which additional regulation is appropriate. However, if the "umbrella" is too small from the beginning, many retail tobacconists will be forced out of business.

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[1] For purposes of taxation, "cigars" are already classified as "small" or "large." Small cigars weigh "not more than 3 pounds per thousand," whereas large cigars weigh "more than 3 pounds per thousand." 26 U.S.C. § 5701.

Accordingly, IPCPR believes that FDA should begin with a subset of the elements proposed, and not include elements that would complicate both enforcement and compliance. In particular, both retail price and "characterizing flavor" seem particularly vague and arbitrary, presenting both enforcement and compliance difficulties.

B. FDA Should Establish by Regulation a "Safe Harbor" Whereby a Retailer Can Rely on a Manufacturer's Representations Regarding the Regulatory Elements of the Cigar

Under either Option 1 or Option 2, FDA would make manufacturers, distributors, importers, and retailers all liable for the actions of one another. Proposed 21 C.F.R. § 1140.10 reads:

> **General responsibilities of manufacturers, distributors, and retailers.**
>
> Each manufacturer, distributor, importer, and retailer is responsible for ensuring that the cigarettes, smokeless tobacco, or covered tobacco products it manufactures, labels, advertises, packages, distributes, imports, sells, or otherwise holds for sale comply with all applicable requirements under this part.

79 Fed. Reg. at 23,204.

This is fundamentally unfair, particularly considering the definition of a "covered cigar" posed by FDA in Option 2. Manufacturers control the different types of tobacco leaf used in the manufacture of the product, and the process of manufacturing the individual cigar, and thus have the greatest ability to determine whether a product meets the proposed exclusionary criteria when it leaves the factory. Retailers are ultimately responsible for how the product is sold, including the retail price.

IPCPR notes that retailers, particularly small or less experienced retailers, may not be able to determine whether a premium cigar meets all of the elements of the definition in the proposed deeming regulations. Because the cigar manufacturer has the greatest ability to determine the materials and means of manufacture, IPCPR believes that FDA should consider limiting the manufacturers' use of the word "premium" or phrase "premium cigar" only to describe cigars that meet all elements of the final definition. For example, a manufacturer could label a cigar or box of cigars as "premium" only if the product complies with all elements of the regulatory exemption, and any other use of the word should be considered misbranding. A retailer must be able to rely on the manufacturer's representation of the product, and not be subject to liability if it is later determined that the manufacturer improperly labeled a "covered cigar" product as "premium." FDA established a retailer "safe harbor" for required warning labels and advertising in the proposed deeming regulations, and FDA should apply the same logic to the retailer's responsibilities for determining whether a product meets the regulatory requirements for an exemption (i.e., whether a cigar is a "premium cigar").

IV. Additional Comments Regarding FDA's Proposed Deeming Regulation

A. Public Health Effects of Premium Cigars are Different than Mass-Market Products Because of Different Usage Patterns, and Thus FDA Should Regulate the Two Categories of Products Differently

Premium cigars should be exempted from regulation given that they have different usage patterns than mass-market tobacco products. Usage data show that premium cigars products are consumed infrequently, often in a celebratory nature, by adults. Premium cigars are also used at a much lower rate than cigarettes, smokeless tobacco, or non-premium cigars. According to a survey conducted by Cigar

Aficionado magazine in May 2009, 43% of respondents smoke two cigars or less per week and 36% reported smoking 3-6 cigars per week (survey data on file). In contrast, most cigarette smokers, for example, smoke daily.

Accordingly, IPCPR believes that FDA's final regulations should not take a one-size-fits-all approach to the regulation of a diverse suite of tobacco products, and should instead impose regulatory requirements for premium cigars consistent with recognized public health differences. IPCPR agrees with FDA's recognition of the risk continuum and believes that FDA should establish a regulatory structure that distinguishes between products on different points of the continuum, as recognized by Option 2. Premium cigars should be exempted from regulation within the scope of the final rule under Option 2, taking into account the revised definition identified above. Should FDA choose to establish some form of regulation, we strongly believe that any rules covering premium cigars should be tailored to match the unique characteristics and public health profile of these unique, artisan products.

B. Studies Indicate That Underage Youths Do Not Smoke Cigars to an Appreciable Extent, and This Should Inform FDA's Decision About Whether to Regulate Premium Cigars

The most current research demonstrates that underage adolescents do not smoke premium cigars to an appreciable degree, and therefore inappropriate "youth access" should not be a consideration when it comes to premium cigars.

The Tobacco Control Act provides that, among its purposes, is to grant FDA "the authority to address issues of particular concern to public health officials, especially the use of tobacco by young people and dependence on tobacco," while at the same time "to continue to permit the sale of tobacco products to adults in conjunction with measures to ensure they are not sold or accessible to underage purchasers." Tobacco Control Act §§ 3(2), 3(7) (emphasis added). The Tobacco Control Act also expressly deprives FDA of authority to issue any regulation "banning all cigarettes, all smokeless tobacco products, all little cigars, all cigars other than little cigars, all pipe tobacco or all roll-your-own tobacco products." 21 U.S.C. § 387g(d)(3)(A). Thus, the statute seeks to balance the public interest in limiting underage exposure to tobacco products, while preserving access to legal tobacco products of choice by adults. FDA may not neglect the latter purpose to fulfill the former, as both are congressionally mandated objectives.

It should be recognized that the purchase or attempted purchase of tobacco products by minors is not a significant issue for premium cigar shops. Firstly, the premium products sold at IPCPR shops are generally not affordable to youth. Secondly, sales in our members' stores are a face-to-face transaction, and in the rare event that an adolescent might try to purchase a tobacco product from a cigar store, the salesperson (frequently the owner of the store) is required to verify the age of the customer. In addition, each new member of IPCPR receives a "We ID" package of signage to use at the point of sale. Thirdly, our members' shops are subject to state and local regulation of tobacco sales, which have proven more than adequate to control underage access to tobacco products from our members' establishments. IPCPR is proud of the compliance record of its members. As FDA noted in the proposed deeming regulations, the Office of the Inspector General for the Department of Health and Human Services ("OIG") has concluded that minors are not attracted to premium cigars, but prefer lower cost and more readily accessible tobacco products. 79 Fed. Reg. at 23,151 (quoting OIG, *Youth Use of Cigars: Patterns of Use and Perceptions of Risk*, OEI-06-98-00030 (Feb. 1999).

FDA should explain more thoroughly why data regarding "young adult males and teenagers" is relevant to underage "youth access" to tobacco products. Notably, FDA cited "a recent analysis of cigar use by young adults (aged 18 to 29) . . . providing preliminary confirmation that young adults do use

premium cigars." 79 Fed. Reg. at 23,151. Fundamentally, tobacco products, including premium cigars, are legal in adults over the age of 18. Elsewhere, the proposed deeming regulation states: "The 2010 National Survey on Drug Use and Health found that over 1 in 10 young adults (ages 18–25 years old) smokes cigars (Ref. 54 at 146, Table 3.5b)." *Id.* at 23,158. As noted above, cigars are legal in that age group.

However, there is data, not discussed in the proposed deeming regulation, regarding actual underage use. Nowhere is this omission more evident than in the proposed deeming regulation's lack of discussion regarding the most recent government data available regarding tobacco product use, released by another agency within the Department of Health and Human Services: The Substance Abuse and Mental Health Services Administration ("SAMHSA"). SAMSHA, *Results from the 2012 National Survey on Drug Use and Health: Summary of National Findings*, NSDUH Series H-46, HHS Publication No. (SMA) 13-4795 (2013) (the "SAMHSA Report"). Figure 4.2 from the SAMHSA Report shows past month tobacco use in youth, ages 12-17 from 2002-2012, which is the underage group that FDA states that it is most concerned about. Figure 4.2 reveals several important facts. Firstly, use of all tobacco products has fallen consistently in this age group from 2002-2012. Secondly, it should be noted that this substantial decrease in tobacco use occurred in the period before FDA obtained jurisdiction over cigarettes and smokeless tobacco. Whether FDA's subsequent activities regarding the regulation of cigarettes and smokeless tobacco will affect this consistent decline in underage use remains to be seen, but FDA should wait to see the results of its efforts before proposing to regulate additional tobacco products. Finally, Figure 4.2 shows that "cigar" use (type of cigar not defined) has never exceeded 5% in any year, and in the last year measured had fallen to 2.6%. A minimal degree of underage use of an otherwise legal product is unavoidable, perhaps for reasons discussed in the proposed deeming regulation (i.e., underage users may obtain tobacco products from social sources such as friends or parents, or from stealing tobacco from parents or others). 79 Fed. Reg. at 23,161. Given the minimal use that actually occurs, a more measured degree of regulation, particularly for premium cigars, would be more appropriate than Option 1 in the proposed deeming regulation.

C. Age Restrictions and Verification Requirements are Appropriate for All Tobacco Products Including Premium Cigars, but a Prohibition on Free Samples is Not Appropriate or Necessary to Prevent Youth Access to Premium Cigars

IPCPR believes that age restriction and verification requirements are reasonable regulatory steps for all tobacco products, including premium cigars sold face-to-face in our members' stores. IPCPR is proud of our organization's and our individual member's constant efforts to help prevent underage access to tobacco products. Each new member of IPCPR receives a "We ID" package of signage to use at the point of sale. Every member of IPCPR is offered free courses through Tobacconist University, IPCPR's Official Education Provider, to become a Certified Retail Tobacconist. The very first obligation under The Code of Ethics & Standards for a Certified Retail Tobacconist is to: "Obey and enforce all local, state and federal laws regarding tobacco age/use restrictions."

The reason given by FDA for imposing a prohibition on free samples is simply not relevant to premium cigars. FDA states that such a prohibition:

> [W]ould eliminate a pathway for youth to access tobacco products, reducing youth initiation and therefore short-term and long-term morbidity and mortality resulting from these products. The Institute of Medicine (IOM) has stated that free samples of cigarettes 'encourage experimentation by minors with a risk free and cost-free way to satisfy their curiosity' (Ref. 26). While the IOM was speaking in the context of

> cigarettes, the same rationale would apply to the proposed deemed products.

Id. at 23,149.

As IPCPR has explained to FDA on several occasions, the same rationale does not apply to premium cigars. In contrast to the historical distribution of free cigarettes, sampling of premium cigars most frequently occurs in a controlled environment, namely, the tobacconist's shop. The professional tobacconist controls who is provided the sample, and requires proof of age. Unlike cigarette smokers, premium cigar smokers exhibit little brand loyalty and "sampling events" are frequently held in premium cigar shops as social occasions to introduce adult premium cigar smokers to limited edition products, seasonal offerings, new brands and varieties, and promote the shop. Often, these sampling events are tied to local community charities. A ban on such practices would have an immediate and significant adverse effect on many small businesses. Sampling is also critically important for premium cigar manufacturers, which frequently introduce new products at much higher price points than other types of cigars. Adult consumers should be permitted to try an expensive new product before they buy it. In addition, IPCPR organizes a trade show for its members where sampling takes place so that retailers can test new products from the manufacturers of premium cigars. We estimate that this annual event creates an economic impact in excess of $15 million to the host city and generates over $750,000 in tax revenues. The show is IPCPR's largest source or revenue. If sampling were banned, IPCPR would likely cease to exist in its present form, leaving a small business industry fragmented without a centralized source of education as to compliance and best practices.

Moreover, a ban would have no effect on the public health since there is no evidence that underage children are obtaining premium cigars from any source to an appreciable extent, much less that sampling is an avenue to such access as demonstrated in the SAMHSA Report.

D. The Proposed Warning Statements Should Not Be Required for Individual Cigars

IPCPR agrees that because premium cigars are frequently sold to adult consumers individually, it would not be practical to require a health warning for such cigars. *Id.* at 23,181. We also note that Option 2 would exempt premium cigars from certain labeling requirements, particularly the requirement that would require warnings on 30% of the principal display panels. Premium cigars are usually packed in decorative boxes, which our customers have come to appreciate as part of the buying experience. As retailers, our humidors are filled with those ornate boxes. Covering 30% of each box with a required warning is more than excessive, particularly when combined with the requirement for a warning sign at the point of sale. In addition, FDA has offered no evidence that requiring a warning covering 30% of a cigar box or 20% of advertising will lead to any appreciable public health benefit. Accordingly, we support the comments of others who have opposed the required warnings.

E. FDA's Economic Impact Analysis Demonstrates That the Financial Burdens Under Option 1 Will be Devastating

FDA estimates that as a result of the costs imposed on manufacturers of premium cigars under Option 1, up to 50% of handmade cigar products will cease to be marketed in the United States. Economic Impact Analysis at p. 26. FDA also notes that small businesses will be most affected by Option 1 and that "some firms may exit the market." *Id.* at 67. Only Option 2 protects the small premium cigar manufacturers and by extension, the IPCPR retailers who sell their products. IPCPR is concerned about the protecting the range of products its members will be able to offer to their adult customers. Being small businesses, our members must have a variety of premium cigar products to offer adult

customers at various price points if they are to survive. Accordingly, IPCPR agrees with the economic impact analyses provided in the comments submitted by others.

F. IPCPR Supports An Exemption For Cigars Rolled Using Hand-Operated, Vintage Cigar Machines

IPCPR includes as an attachment our comments in support of an exemption for cigars rolled using hand-operated, vintage cigar machines. There are three small factories left in the United States producing a very small number of cigars in this manner and an exemption would protect US jobs. IPCPR agrees with the comments submitted by the JC Newman Company, and others regarding extending the exemption to these cigars. IPCPR also wishes to take this opportunity to express its appreciation for the many members of Congress who have supported an exemption for premium cigars including cigars rolled using hand-operated, vintage cigar machines as expressed in H.R. 792 and S. 772.

* * * *

IPCPR appreciates having this opportunity to comment on the proposed deeming regulation.

Sincerely,

Finnie Helmuth
President
International Premium Cigar & Pipe Retailers Association

Craig Cass
First Vice President
International Premium Cigar & Pipe Retailers Association

Mark Pursell
CEO
International Premium Cigar & Pipe Retailers Association

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August 7, 2014

VIA ELECTRONIC FILING

Division of Dockets Management (HFA 305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, Maryland 20852

Re: Docket No. FDA-2014-N-0189

Dear Sir or Madam:

The International Premium Cigar & Pipe Retailers Association ("IPCPR") understands there are three historic factories in America that still roll cigars using hand-operated, vintage cigar machines:

- Avanti Cigar Co. in Dunmore, Pennsylvania
- J.C. Newman Cigar Co. in Tampa, Florida
- National Cigar Co. in Frankfort, Indiana

These factories make a fraction of the cigars sold annually in the United States, but are historic and family owned. IPCPR believes that hand-operated, vintage machine-made cigars should be treated the same as premium cigars because they have the same look, feel, smell, and taste as value-priced handmade cigars. They have the same style of packaging, and have similar retail prices. They are often sold by IPCPR members, on the same shelves as other value-priced premium cigars. Like premium cigars, they present minimal public health and youth access issues, and consumers perceive these cigars to be just like value-priced premium cigars.

As vintage machine-made cigars are wrapped in 100% natural leaf tobacco, they look very different from modern mass-market machine-made cigars, which have a homogenized tobacco wrapper. Vintage machine-made cigars are also sold in different retail outlets at different price points, and have a different type of consumer than modern mass-market cigars. Moreover, hand-operated, vintage cigar machines roll approximately 840 cigars per hour, a small fraction of the 225,000 cigars per hour made by modern mass-market cigar machines. It would be cost-prohibitive or technically impossible (and defy logic) for mass-market cigar companies to slow their machines from 225,000 cigars per hour to less than 1,500 cigars per hour or to than 1% of their current rate in an attempt to evade regulation.

As FDA knows, IPCPR has long supported a statutory exemption for premium cigars. The current form of the proposed legislation is the Traditional Cigar Manufacturing and Small Business Jobs Preservation Act (H.R. 792 and S. 772, which are identical bills). This proposed legislation would exempt both handmade premium cigars, and hand-operated, vintage machine-made cigars made in the United States from FDA regulation. The bill defines the "hand-operated machine made" cigar as:

> A]ny roll of tobacco that is wrapped in 100 percent leaf tobacco, bunched with 100 percent tobacco filler, contains no filter, tip or non-tobacco mouthpiece, weighs at least 6 pounds per 1,000 count, and . . . has a homogenized tobacco leaf binder and is made in the United States using human hands to lay the 100 percent leaf tobacco wrapper onto only one machine that bunches, wraps, and caps each individual cigar; and does not include a cigarette (as such term is defined by section 900(3)) or a little cigar (as such term is defined by section 900(11)).

H.R. 792, 113th Cong. § 2(a) (2013).

This definition is narrowly tailored to include only the hand-operated, vintage machine-made cigars from these American factories. Due to the high costs and limited supply of 100% natural leaf tobacco wrappers, it would, without a doubt, be cost prohibitive for mass-market cigar makers to change their production processes to meet this definition. More importantly, the process cannot be used by other companies. These cigars should be treated as FDA determines to treat cigars that meet the "premium" definition.

* * * *

IPCPR appreciates having this opportunity to comment on the proposed deeming regulation.

Sincerely,

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