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**Submitting Comments to the FDA on Tobacco Deeming Regulations**

NATO is asking all association members, including retailers, wholesalers, and manufacturers, to submit comments to the FDA’s Center for Tobacco Products on the proposed tobacco deeming regulations. The process to submit comments to the FDA is simple and this bulletin provides easy to follow step-by-step instructions on how to send in comments to the FDA. While the FDA has extended the deadline to submit comments to August 8, 2014, the time to submit comments is now and the information below will assist you in submitting comments.

**Step 1: How to Submit Comments to the FDA**

Comments can be submitted to the FDA’s Center for Tobacco Products either by mail or over the Internet on the [www.regulations.gov](http://www.regulations.gov) website:

 **A. By Mail:** Division of Dockets Management (HFA-305)

 Food and Drug Administration

 5630 Fishers Lane, Rm. 1061

 Rockville, MD 20852

 Note: At the top of your letter, you need to type in the following line: **RE: Docket No. FDA-2013-N-0189 and RIN 0910-AG38.**

 **B. On the Internet** (Click on the link below or type the address in your browser and press enter):

 http://www.regulations.gov/#!submitComment;D=FDA-2014-N-0189-20870

 1. The [www.regulations.gov](http://www.regulations.gov) webpage will appear on your screen and should state across the top “You are commenting on the Food and Drug Administration (FDA) Proposed Rule: Deeming Tobacco Products to be Subject to the 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.

 2. Under Number 1, “Your Information”, you can either type or copy and paste your comments into the box beneath the word “Comment” or scroll down and upload your comments if you typed a letter on your computer. To upload your comments, click “Choose files”, a listing of the documents on your computer should appear on your screen, locate and then double click the letter that you want to upload. (**Note: Please use your own words in typing your comments and see suggested points to make in your comments below under Step 2: What Should You Say in Your Comments).**

 3. You may, but are not required to, fill in the boxes labeled “First Name” and “Last Name”.

 4. If you want to provide your zip code and e-mail address, click on the box in front of “I want to provide my contact information” and then type in your zip code and e-mail address in the appropriate boxes. Providing this information is optional.

 5. If you are submitting comments for someone else (for example, your attorney is drafting comments to submit on behalf of your company), the person submitting the comments will need to check the box in front of “I am submitting on behalf of a third party” and type in his/her name and your company’s name. However, if you are submitting your own comments, do not check the box.

 6. The next box is titled “Category” and an answer must be selected. Click on the down arrow box and then select “Private Industry” if the comments are being submitted by you as a retailer, wholesaler or manufacturer. If you or your customers desire to submit your own individual comments, click “Individual Consumer”.

 7. Then, click the blue “ Continue” button and you are taken to the “Your Preview” page. If all of the information is correct, scroll down, read the filing statement and then click on the small box in front of the phrase “I read and understand the statement above.”

 8. Finally, click the blue “Submit Comment” button to submit your comments. You will then be provided a receipt for the submission of your comments.

**Step 2: What Should You Say in Your Comments?**

The FDA has proposed two deeming regulatory options. Option 1 would extend the agency’s regulatory authority to all other categories of tobacco products including cigars, pipe tobacco, electronic cigarettes, nicotine gels, hookah tobacco and dissolvables, except accessories of a tobacco product. Exempt accessories would include such items as lighters, cigar cutters, humidors, cases, and hookah tobacco tongs, charcoal burners and holders. Under Option 2, the FDA’s regulatory authority would be extended to all of the tobacco products under Option 1, except premium cigars and accessories of a tobacco product. The FDA’s proposed rule to extend its authority is contained in the accompanying 241-page document. The first 218 pages provides an explanation of the FDA’s rationale for the proposed regulations as well as questions being asked by the agency for the public to provide input. The actual proposed regulations are found on Pages 219-241.

Below is a list of suggested comments on premium cigars, pipe tobacco, and electronic cigarettes. Depending on your kind of retail store and the tobacco products that you sell, you may want to include some or all of the comments when you submit comments to the FDA. The text in blue is suggested comments for you to consider including in your comments. The text in red is information that should not be included in your comments.

To assist NATO members in submitting comments, consider the following guidelines:

 A. Begin your letter or comments with Dear FDA Staff, or Dear FDA Representative.

 Remember, if you are mailing a letter to the FDA, include “RE: Docket No. FDA-2013- N-0189 and RIN 0910-AG38” at the top of the letter.

 I am writing to submit my comments on the proposed deeming tobacco product regulations.

 B. Provide some background information such as your company’s name (unless you want to remain anonymous), number of stores or warehouses you operate, and the number of people you employ.

 C. Retailers: Include a statement that you and your employees responsibly sell tobacco products to adult customers and work diligently to comply with state and federal laws regarding the sale of tobacco.

 D. Suggested Comments on Premium Cigars

 The proposed definition of a premium cigar should not include a minimum retail price of $10 per cigar. This price point is unrealistic and arbitrary because a significant majority of premium cigars have a retail price below $10, with many premium cigars priced substantially less than $10 per cigar.

 The FDA should not prohibit flavors in premium cigars, other than a “tobacco” flavor. Premium cigars are not a standardized product, but are manufactured in many different sizes, shapes, tobacco blends, or flavors. The variation in tobacco blends used in making premium cigars means that approximately 90% of these cigars could be considered to have a characterizing flavor other than the allowed “tobacco” flavor. Banning cigar flavors, other than tobacco, would result in a ban on the sale of the vast majority of premium cigars. As a result, family-owned retail businesses that sell premium cigars would lose a substantial amount of cigar sales, causing job loss and the closure of specialty tobacco stores. What would flourish is a black market for contraband premium cigars and make the current black market for Cuban cigars even worse. A federal agency should not adopt a regulation that financially impacts law-abiding manufacturers, wholesalers and retailers while creating the conditions for or expanding a black market.

 The sampling of the premium cigars is a retail tradition and is essential for adult consumers to try new cigars and cigars with different flavors. Oftentimes, a tobacco store will have special cigar sampling events. For example, manufacturers will assist retailers in holding a special cigar tasting, much like a wine tasting event at a liquor store. These special cigar tasting events are very important for retailers to expand their sales. With underage youth not invited to these cigar sampling events, there is no risk that a minor would have access to cigars.

 E. Suggested Comments on Pipe Tobacco

 Many tobacco retailers that sell pipe tobacco blend two or more pipe tobaccos together to develop different flavors of pipe tobacco. Since the pipe tobacco manufacturers would have already registered the pipe tobaccos that are being blended together, are retailers that blend registered pipe tobaccos be considered a “manufacturer” under FDA regulations? A tobacco retailer would not have the expertise or financial ability to comply with all of the product registrations and filings. This means that tobacco retailers would be prohibited from blending pipe tobaccos resulting in a substantial loss of pipe tobacco sales.

The FDA should consider providing an exemption to allow tobacco retailers to blend an aggregate of up to 5,000 pounds of pipe tobacco a year without the retailer being subject to pipe manufacturer regulations provided that the primary manufacturers of pipe tobaccos have already complied with all FDA regulations. To require both the primary manufacturer and a tobacco retailer to register pipe tobaccos and file product ingredient lists would be redundant. Pipe tobaccos blended together retain their same characteristics after the blending occurs, except for a new flavor when smoked in a pipe. Since the FDA is not proposing to regulate pipe tobacco flavors, and that is the only characteristic that changes when pipe tobaccos are blended, then retailers that blend pipe tobacco should not be considered manufacturers of pipe tobacco.

 In the event that the FDA would require retailers that blend pipe tobaccos to be manufacturers, then retailers would be forced to choose between no longer selling blended pipe tobacco or selling the proper amount of the different pipe tobaccos in separate sealable bags with instructions for the customer to take the bags home, open the bags, and mix the different pipe tobaccos together to obtain the blended pipe tobacco product. This situation will only create an inconvenience for customers and cause retailers who want to save their business to resort to the alternative method of selling separate bags of pipe tobacco to customers to avoid being regulated as a manufacturer. Retailers want to comply with the law, provided that the law is fair and reasonable, and not be forced to find alternative means to continue to sell a deemed tobacco product.

 Certain descriptive words are used to describe a blend of pipe tobacco such as “mild”. However, in contrast to the use of the banned descriptor words like “mild” for cigarettes, the term “mild” when applied to pipe tobacco does not mean that there is less risk or the product is less harmful. Rather, the term relates to the pipe tobacco’s flavor and is being used to reflect the fact that the pipe tobacco does not have a bite or harshness when smoked. For this reason, descriptive words should be allowed to be used regarding pipe tobacco.

 The sampling of the pipe tobacco is a retail tradition and is essential for adult consumers to try new pipe tobacco blends with different flavors. Oftentimes, a tobacco store will have special pipe sampling events. These special pipe tobacco sampling events are very important for retailers to expand their sales. With underage youth not invited to these sampling events, there is no risk that a minor would have access to cigars.

 F. Suggested Comments on Pre-Market Applications for Cigars, Pipe Tobacco, and Electronic Cigarettes

**[Premarket Review Background: Do Not Include in Comments: For cigars, pipe tobacco, and electronic cigarettes, that were not on the market as of February 15, 2007, manufacturers of these products would need to submit a premarket tobacco application (PMTA) to the FDA within 24 months following the effective date of the final deeming regulations. If a PMTA application is filed with the FDA during this 24-month period, then the manufacturer can continue to market its products unless and until the FDA responds to the application. The standard to be used by the FDA in reviewing PTMA’s will be whether the tobacco product is appropriate for the protection of the public health or detrimental to the public health.]**

The pre-market application process will be costly and time consuming for cigar manufacturers and could result in many cigar brands, pipe tobacco brands, and electronic cigarettes being removed from the marketplace. If this occurs, our retail sales of these products could decline substantially and negatively impact our business.

Cigars come in numerous shapes and sizes with variations in cigar tobacco as well as limited manufacturing of special edition cigars and seasonal blend cigars. This constant variation in cigar tobacco used to make premium cigars and the limited number of cigars manufactured for special editions and seasonal blends will create significant regulatory burdens and costs for cigar manufacturers to be constantly filing pre-market tobacco applications. Those cigar manufacturers that are unable to bear the cost of pre-market tobacco applications will cease bringing new products to the marketplace.

Pipe tobacco manufacturers will incur the same cost and time burdens if they were required to file pre-market tobacco applications for each new blend of pipe tobacco that they manufacture.

Regarding electronic cigarettes, since there were no similar products on the market prior to February 15, 2007, each electronic cigarette manufacturer would need to file a pre-market application for every brand of electronic cigarette currently being sold and new electronic cigarettes introduced into the marketplace. Electronic cigarette manufacturers may not have the financial resources to file pre-market applications resulting in the removal of these brands of electronic cigarettes from the marketplace.

 G. Suggested Comments on Minimum Age of 18 to Purchase Deemed Tobacco Products

Retailers support a minimum age of 18 years old to purchase cigars, pipe tobacco, electronic cigarettes, hookah tobacco, dissolvables, and nicotine gels. This is the same minimum age required for the purchase of cigarettes, roll-your-own tobacco, and smokeless tobacco products at the state level, except for Alabama, Alaska, New Jersey and Utah, which have a minimum age of 19.

Establishing a minimum legal age for purchasing the deemed tobacco products is an issue of responsibility. Retailers are responsible people who are not in the business of selling tobacco products to minors.

 Also, retailers support requiring age verification through photo identification of a customer who is younger than 27 years old. Retailers are accustomed to complying with this age verification requirement for cigarettes, roll-your-own, and smokeless tobacco products and continuing the policy for the deemed tobacco products is appropriate.

 H. Suggested Comments on Banning Flavors in Little Cigars and Other Non-Cigarette Tobacco Products

  **[Tobacco Product Flavor Background: Do Not Include In Comments: The proposed deeming regulation does not ban flavors for the deemed tobacco products. The ban on flavors, except tobacco and menthol, continues to only apply to cigarettes. However, the FDA is requesting comments on factors it should consider in determining whether a particular tobacco product such as a little cigar or other non-cigarette tobacco product could be characterized as a “cigarette” and thus subject to the current flavor ban].**

 The FDA is overreaching when it requests public comments on whether a little cigar or other non-cigarette tobacco product could be characterized as a “cigarette” and then subject to the current cigarette flavor ban. Every kind of tobacco product is individually defined under federal law and this request by the FDA is an attempt to redefine various tobacco products as if they are cigarettes in order to impose a flavor ban. The FDA is not a legislative body and, for that reason, cannot change legal definitions of tobacco products under federal law to support a regulation banning flavors in little cigars and other tobacco products that could be considered a cigarette.

I. Closing Comment

 Thank you for the opportunity to submit comments on the tobacco deeming regulations.

**Will Submitting Comments to the FDA Make a Difference?**

**The most direct and simple answer to this question is “yes”. The FDA is required to seek public comments on proposed regulations just like it is doing now on the extension of the agency’s regulatory authority to cigars, pipe tobacco, electronic cigarettes, hookah tobacco, nicotine gels, and dissolvables. Moreover, FDA staff members have indicated to NATO and publicly stated that they read every comment that is submitted. It is very important that members of the tobacco industry, including retailers, wholesalers and manufacturers, all submit comments to the FDA.**