Let Your Voice Be Heard: FDA’s Proposed Deeming Regulation for Tobacco Products

On April 25, 2014, FDA published a proposed regulation extending its jurisdiction to various “deemed” tobacco products, including electronic cigarettes. If made final, the proposal would subject deemed products to a number of significant regulations that would apply automatically by virtue of a product being “deemed.” A full summary of the proposed rule assembled by the Campaign for Tobacco Free Kids can be found here.

The FDA is seeking comments and evidence from professionals, so this is your opportunity to provide your personal feedback and observations to the agency. After a recent 30 day deadline extension issued by the FDA all comments are due to the FDA by Friday August 8th at 11:59 PM EST. Comments should be submitted electronically through the federal register found here. Below are some suggested comments (in bold):

- **ISSUE 1: Potential Premium Cigar Exemption:** The proposed rule contains two alternative proposals for FDA oversight of cigars and asks for public comment on which alternative FDA should adopt. Under one option, all cigars and other tobacco products would be made subject to FDA jurisdiction. Under the other option, all tobacco products would be regulated with an exception for premium cigars.

  Support FDA regulation of ALL tobacco products including premium cigars. For more suggested comments, see the May 2014 letter signed by the AAO-HNS and other organizations.

- **ISSUE 2: Marketing and Advertising:** The FDA has specific rules restricting the advertising and marketing of cigarettes and smokeless tobacco products. However, the proposed rule does not address the advertising and marketing of newly deemed products such as cigars or e-cigarettes.

  Urge the FDA to exercise its authority over advertising and marketing of newly deemed products and address any marketing strategies that may have public health ramifications.

- **ISSUE 3: Product Standards and Flavorings:** Once the proposed rule is finalized, the FDA will have the same authority to issue product standards applicable to the newly-deemed tobacco products, including flavorings used to appeal to young people. While the FDA has the statutory authority to issue a product standard prohibiting flavorings in the newly-deemed products, the proposed rule itself does not prohibit flavorings in any deemed tobacco products.

  Urge the FDA to exercise its statutory authority to issue product standards regarding flavorings, particularly for cigars and e-cigarettes.

- **ISSUE 4: New Products:** Under the Tobacco Control Act (TCA), any product not commercially marketed on or before February 15, 2007, or modified after that date, is defined as a “new tobacco product.” No new tobacco product may be marketed until a manufacturer has filed an application with the FDA, and the FDA has issued a marketing order for that product.

  Encourage the FDA to institute a strict, yet succinct, process for evaluating these applications and to close any gaps/loopholes left open by the proposed rule.
• **ISSUE 5: Two-Year Window for New Products:** The FDA proposes to permit manufacturers of newly-deemed tobacco products the ability to keep their current products on the market, as well as to introduce new products, without FDA marketing orders provided that the manufacturer files a new product application or a substantial equivalence application for that product within two years of the date the proposed rule is finalized.

Encourage the FDA to narrow this window so that any tobacco products that may have adverse or unknown public health ramifications are not in circulation while undergoing the application review process.

• **ISSUE 6: Warning Labels:** The FDA’s proposal establishes five new warning labels for cigars. For cigars sold individually and not in a product package, no warning needs to be placed on the products. Instead, the warning statements must be posted at the retailer’s point-of-sale. For all other newly covered products and other regulated products for which there were no required warning labels, the FDA has only established one warning label. “WARNING: This product contains nicotine derived from tobacco. Nicotine is an addictive chemical.”

Ensure the FDA is aware of the potential health risks that nicotine poses and that a warning label more closely reflects that nicotine is a powerful and potentially harmful substance.

For questions or if you would like to forward a copy of your comments to the AAO-HNS, please contact HealthPolicy@entnet.org.