



## Urge the FDA to Strengthen the Proposed Deeming Regulation

On April 25, 2014, the U.S. Food and Drug Administration published a proposed rule to allow the agency to begin regulating all tobacco products. The FDA has been regulating cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco since the Family Smoking Prevention and Tobacco Control Act was passed in 2009, but without this proposed rule, the FDA cannot regulate e-cigarettes, cigars, “little cigars,” dissolvable products, or hookah.

While the FDA has taken an important step, the proposed rule leaves many gaps in regulation that must be addressed. In order for the FDA to improve the proposed regulation, it needs to receive strong support and evidence from public health advocates and professionals.

The FDA is accepting public comments on the proposed rule until July 9, 2014. In developing your comments, consider addressing the following issues:

- While the FDA’s proposal recognizes that fruit and candy flavors can be especially attractive to youth, the FDA has not proposed to extend the current prohibition on characterizing flavors for cigarettes to any other products. If the proposed rule is not strengthened, e-cigarettes and other tobacco products will continue to be marketed and sold in youth-attractive flavors.
- Although the FDA has the authority, it has not proposed any advertising and marketing restrictions for newly covered tobacco products.
- The FDA proposal would significantly delay the enforcement of several basic and important provisions in the Tobacco Control Act, appearing to prioritize tobacco industry business interests at the expense of public health. These delays would apply to:
  - Required identification of the manufacturer on tobacco product packages
  - Required submission of lists of tobacco product ingredients
  - Required submission of lists of harmful and potentially harmful constituents
  - Required submission of health information
  - Required registration of manufacturers
  - Required submission of product lists
  - Prohibition on the terms “light,” “low,” “mild,” and similar descriptors
- The FDA proposal would significantly delay the implementation of premarket review for newly covered products. Most egregiously, the proposal creates a twenty-four month provisional period for the submission of tobacco product marketing applications.

Applications received during the provisional period enable the continued marketing of the product until the FDA acts on the application – which may be well beyond the twenty-four month period. A similar loophole was established during the passage of the Act to apply to cigarettes and smokeless products. The FDA received 3,517 applications but three years later has only issued an order removing four products from the market. After the withdrawal of 117 applications, the tobacco companies are still able to market the unapproved products represented by the 3,396 outstanding applications.

- Restrictions related to youth access, vending machines and sampling, as well as warning label requirements, will apply to newly covered tobacco products but not to their components or parts that do not contain nicotine. This proposed exemption could create compliance and enforcement problems, especially related to e-cigarettes. The FDA will have to enforce these requirements and restrictions on nicotine-containing e-cigarettes and nicotine refill cartridges but not for any part of an e-cigarette device that contains no liquid or refill cartridges that are free of nicotine. If the regulation is finalized without changing this, state and local governments will have to fill in the gaps to regulate the parts and components that the FDA is exempting.
- The FDA’s proposal establishes four new warning labels for cigars but 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.*” This is the only warning that will appear on packages of e-cigarettes, dissolvables, roll-your-own tobacco, pipe tobacco, and hookah. Compare this to existing federal law, which establishes nine warning labels for cigarettes and four warning labels for smokeless tobacco. The sole proposed warning label fails to include any of the known harmful effects of nicotine beyond addiction. In addition to omitting important health information, proposing only one warning for these products means that there can be no rotation of warning statements as there is for other products. This warning label will likely grow stale and soon have little effect on consumers.
- There are many restrictions that apply to cigarettes and smokeless tobacco which the FDA should extended to newly covered products to maximize immediate benefits to public health. For example, the proposal does not include requirements related to: minimum package sizes, prohibition on breaking packages by retailers, prohibition on tobacco brand names on non-tobacco products, prohibition on brand name sponsorship of sporting and cultural events.

For more resources related to this proposed rule, visit the [FDA Tobacco Action Center](#). In addition, Consortium attorneys are available to help you develop your comments.