Just the Facts: FDA Deeming Other Tobacco Products under Its Authority

A Proposed Rule

On April 24, 2014, the Food and Drug Administration (FDA) released its proposed rule to deem other tobacco products under its authority and the Family Smoking Protection and Tobacco Control Act. Additionally, the proposed rule seeks to apply three specific provisions to the newly deemed tobacco products for the protection of public health.

This factsheet will review:

- **Deeming**
- **Other Provisions**
- **Request for Comments & Next Steps**

Most importantly, because this is a proposed rule, FDA is seeking comments, data, and research on the proposed actions in the rule.

Deeming

At this time, only cigarettes, roll-your-own-tobacco, and smokeless tobacco are subject to regulation under the Tobacco Control Act. The law does allow FDA to "deem" other tobacco products under its authority, and subject those products to the provisions of the Tobacco Control Act. Under this proposed rule, FDA is proposing to bring all other categories of tobacco products, including certain dissolveables, gels, hookah tobacco, electronic cigarettes, cigars, and pipe tobacco, under its authority. FDA does specifically ask for comments as to whether premium cigars should be excluded from its authority.

There are several provisions of the Tobacco Control Act that these products would be subject to if deemed in the final rule. These include:

- Enforcement action against products determined to be adulterated and misbranded
- Required submission of ingredient listing and reporting of harmful and potentially harmful constituents for all tobacco products to the FDA
- Required registration and product listing for all tobacco products
- Prohibition against use of modified risk descriptors (e.g. "light" or "mild") and claims (e.g. one product is less harmful than another product) unless FDA issues an order permitting such a claim
- Prohibition of free samples (same as for cigarettes)
- Premarket review requirements

FDA has proposed that these automatic provisions take effect 30 days after publication of the final rule. Additionally, FDA has proposed compliance dates for these provisions in a framework that mirrors what the requirements were for cigarettes, roll-your-own-tobacco, and smokeless tobacco when the law took effect.

Three Specific Provisions

In addition to "deeming," FDA is proposing three specific provisions be applied to newly deemed tobacco products. They are:

(1) Prohibiting retailers from selling newly deemed tobacco products to persons under the age of 18 and requiring photo identification;

(2) Prohibiting the sale of newly deemed tobacco products from being sold in vending machines, except in adult-only facilities; and
(3) Requirements for warning statements on products and advertisements.

These provisions already apply to cigarettes, roll-your-own-tobacco, and smokeless tobacco under the Tobacco Control Act. FDA has proposed that the minimum age and vending machine restrictions take effect 30 days after publication of the final rule. FDA has proposed that the warning statements appear on products and advertisements 24 months after publication of the final rule, with a 30 day grace period for any remaining inventory. These are the only specific provisions in the proposed rule; it does not address the marketing or advertising of these proposed deemed tobacco products, or flavorings in these products.

Request for Comments & Next Steps

FDA has established a75-day open comment for the public to submit written comments about the proposed rule. In the proposed rule, FDA requests information, data, and research on many specific questions, as well as comments on the provisions mentioned above and the overall rule. Some of the topics addressed in those questions include:

- Whether premium cigars should be regulated, and if they should be regulated the same as other cigars
- Whether a tobacco product meets the definition of a 'cigarette' as opposed to another tobacco product (e.g. a little cigar), and therefore should be regulated as a cigarette
- The use of characterizing flavors in tobacco products, especially their attraction to youth and long-term effects
- Any information and data on e-cigarettes, since they are a new product
- Whether tobacco product accessories (e.g. lighters) should be regulated, and if/how tobacco product components (e.g. tubes or papers) and accessories should be regulated
- Establishing pathways for newer products to enter the market that cannot, because of dates written into the Act, apply as a substantial equivalence product
- Appropriate compliance dates for provisions

Once the comment period closes, FDA will review all comments and develop the Final Rule for publication in the Federal Register.

The Proposed Rule can be found here.

The **American Cancer Society Cancer Action Network** supports a comprehensive approach to addressing tobacco use and exposure to secondhand smoke in the United States. Our advocacy strategy includes:

- Increasing the price of all tobacco products through tobacco tax increases
- Implementing comprehensive smoke-free policies in communities and states
- Fully funding and sustaining evidence-based, statewide tobacco prevention and cessation programs, including ensuring access to clinical cessation services
- Working with the Food and Drug Administration to effectively implement the Family Smoking Prevention and Tobacco Control Act to comprehensively regulate tobacco products and their marketing

Each component works in conjunction with the others and all are necessary to tackle the tobacco epidemic in this country effectively. ACS CAN works in partnership with federal, state, and local policymakers across the country to ensure that tobacco use is addressed comprehensively in each community.