Summary of the Proposed Tobacco Product Standard for Characterizing Flavors in Cigars

Why did this happen?

Despite a general decrease in tobacco consumption over the past ten years, the FDA has identified flavored cigars as a tobacco product category increasingly favored by under-age smokers at a rate near that of cigarettes. FDA believes eliminating this category will lead to reduced youth consumption of tobacco, particularly among minority populations.

What kinds of products are being prohibited?

Any cigar that would be characterized as having a flavor that is not tobacco. This refers to flavors present when the tobacco is unlit, or which are produced in the smoke.

"This proposed rule, if finalized, could lead adult flavored cigar smokers to cease tobacco use, reduce tobacco use, or encourage them to switch to other, potentially less harmful tobacco products."[1]

"Prohibiting characterizing flavors (other than tobacco) in cigars would reduce the appeal of cigars, particularly among youth and young adults, and decrease the likelihood that nonusers would experiment with cigars. It also would decrease the likelihood that current experimenters would continue to use these products. Reducing the appeal of cigars and experimentation is particularly important because, as experimenters continue to use these products, they can develop dependence, leading to regular use and increasing their risk of developing the many negative health consequences associated with regular cigar use."[2]

What is "characterizing flavor"?

Characterizing flavor refers to the sensory experience of the cigar. The rule does not distinguish between cigars that acquire flavors through natural processes, additives or infusion. Common characterizing flavors for cigars include sweet, fruits, herbs, spices, and spirits.

"FDA (...) would prohibit a cigar or any of its components or parts (including the tobacco, filter, or wrapper, as applicable) from containing, as a constituent (including a smoke constituent) or additive, an artificial or natural flavor (other than tobacco) or an herb or spice, including, but not limited to, strawberry, grape, orange, clove, cinnamon, pineapple, vanilla, coconut, licorice,

[1] Department of Health and Human Services, Food and Drug Administration, Tobacco Product Standard for Characterizing Flavors in Cigars., 31
[2] Ibid., 70, 71

cocoa, chocolate, cherry, coffee, mint, or menthol that is a characterizing flavor of the tobacco product or tobacco smoke" [3]

What about cigars with ambiguous flavors that cannot be commonly identified?

The rule applies to any non-tobacco flavors. This includes sensations such as sweet, spicy, cool. etc.

What about adding flavor to the tip or mouthpiece of a cigar?

For the purpose of the regulation, the cigar is defined to include any of its components. This includes, but is not limited to, tips, mouthpieces, blunt wrappers or flavorings intended to be added by the consumer.

What about aging processes that affect the flavor of the cigar tobacco?

The rule does not address cultivation, processing or manufacturing standards for cigar tobacco outside of prohibiting flavoring or additives.

What about tobacco that takes on flavor through natural exposure, such as barrel aging?

The rule speaks to the resulting flavor of the cigar. If after barrel aging, the cigar's taste experience would be characterized as something other than tobacco, it would be prohibited. If the cigar were barrel aged, but retained the characteristic flavor of tobacco, it would be permissible.

How does this affect advertising and sales of cigars?

The proposed rule prohibits use of explicit or implicit use of flavor descriptors in labeling or advertising, that characterizes cigars as other than tobacco. It is unclear to what extent the rule

attempts to restrict the description of natural variances in tobacco flavor, as is commonly done with premium cigars.

How will this affect traditional pipe tobacco?

As drafted, the proposed rule does not affect pipe tobacco. FDA indicated that pipe tobacco is unpopular with youth, nor do they see pipe tobacco as a substitute for cigars. However, FDA leaves open the opportunity for additional public comment on the question of flavored pipe tobacco.

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[3] Ibid., 11, 12

When will this take effect?

Following a 60-day comment period, FDA will review all comment materials, draft responses and make changes to the regulation before publishing a Final Rule. The Proposed Rule indicates the regulation will take effect one year after the Final Rule is published.

What do I do with my current stock?

As a Proposed Rule, there is no new restriction in effect today. Retail business can operate normally, and PCA will provide timely updates throughout the regulatory process.

Can rulemaking be stopped?

The rulemaking process can be stopped by FDA at any time or change in law by Congress can strip them of authority necessary to proceed. Once published as a Final Rule, a successful legal action can limit implementation of a rule or strike a rule entirely.

Who can submit a public comment?

Individual customers, retailers, manufacturers, and trade organizations have the ability to submit public comments. PCA will be compiling talking points for submitting public comments when the docket opens. Public comments need to be rooted in data, scientific conclusions, and evidence-based information. Public comments submitted to the regulatory docket are not the same as writing to an elected official that is accountable to voters and should not be emotional appeals.

How can I submit a public comment?

All submissions received must include the Docket No. FDA-2021-N-1309 for "Tobacco Product Standard for Characterizing Flavors in Cigars." Received comments, those filed in a timely manner will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402- 7500.

Submit electronic comments in the following way: Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged.

Submit written/paper submissions as follows: Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

For questions or comments please contact us using the information below:

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References

Department of Health and Human Services, Food and Drug Administration, Tobacco Product Standard for Characterizing Flavors in Cigars, 21 CFR Part 1166 [Docket No. FDA-2021-N-1309] RIN 0910-AI28