


What's New in the World of Combustible Tobacco Products

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ITG Brands, LLC

What's *REALLY* New?

- Decisions on Exempt Requests
- Decisions on Substantial Equivalence Applications
- Tobacco Product Application Workshop
 - Notification Appendix
 - 180 days

What's Pending?

- Tobacco Product Standard for Nicotine Level of Combusted Cigarettes ANPRM
 - 7,890 Comments
 - Gottlieb: FDA's proposed rule this summer

What's Pending?

- Tobacco Product Standard for Nicotine Level of Combusted Cigarettes ANPRM
 - Pending
 - Science and technical achievability dependent upon level
 - Tax and Illicit Trade Impact
 - Less *harmful* products and pathways to market

What's Pending?

- Content and Format of Substantial Equivalence Reports; Proposed Rule
 - Comments due June 17, 2019

What's Pending?

- Content and Format of Substantial Equivalence Reports; Proposed Rule
 - Pending
 - Product Quantity SE
 - Container closure system
 - Definitions:
 - Same characteristics
 - Different characteristics
 - Different questions of public health

What's Pending?

- November 15, 2018:
 - We will advance a Notice of Proposed rulemaking that would seek to ban menthol in combustible tobacco products; including cigarettes and cigars, informed by the comments on our Advance Notice of Proposed Rulemaking (ANPRM) Regulation of Flavors in Tobacco Products
 - Has the science changed??


What is needed?

- TPMP
- Complete SE rule-
 - Definitions of same and different characteristics
 - Different questions of public health?
 - Variability tolerances
 - Product category-specific guidance

What is needed?

- Expansive track record on PMTA and MRTPAs to allow combustible consumers to understand risk continuum and OPTIONS
 - Where is the risk continuum discussion?
- Clear decision documents or decision trees

Thank you



What's New in the World of Combustible Tobacco Products

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Advanced Notices of Proposed Rulemaking

- ANPRM on “Tobacco Product Standard for Nicotine Level of Combusted Cigarettes”
 - “FDA is seeking comment on whether the standard should cover any or all of the following products:
 - Combusted cigarettes (including kreteks and bidis)
 - Some or all cigars
 - Pipe tobacco
 - Cigarette tobacco
 - Roll-your-own tobacco
 - Waterpipe tobacco”

Advanced Notices of Proposed Rulemaking

- ANPRM on the “Regulation of Premium Cigars”
 - “the regulatory considerations with respect to premium cigars, their use, and related public health issues continue to be of significant interest to some stakeholders, as well as a topic of ongoing and emerging research”
 - How to define a premium cigar
 - Use patterns of premium cigars
 - Public health considerations associated with premium cigars

Advanced Notices of Proposed Rulemaking

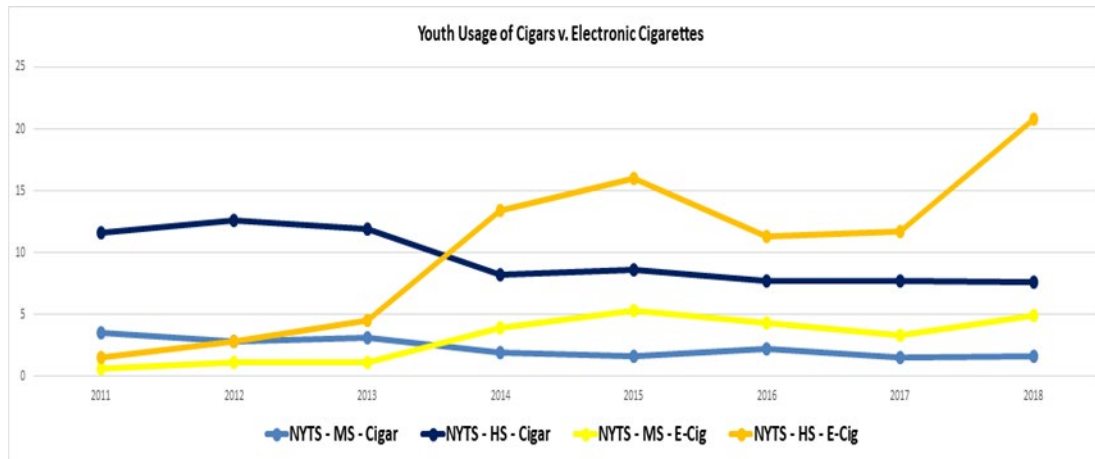
- ANPRM on “Regulation of Flavors in Tobacco Products”
 - What is a “flavor”?
 - FDA is seeking information relating to the following (as applicable): (1) Artificial or natural flavor additives, compounds, constituents, or ingredients or any other flavoring ingredient in a tobacco product, including its components or parts; (2) the multisensory experience of a flavor during use of tobacco products; (3) flavor representations (including descriptors), either explicit or implicit, in or on the labeling, advertising, and packaging of tobacco products; and (4) any other means that impart flavor or represent that tobacco products are flavored.
 - What products should be covered by any proposed product standard?
 - If FDA were to establish a tobacco product standard prohibiting or restricting flavors, to which types of tobacco products should the standard apply (e.g., combusted, noncombusted, both), and why?

Draft Guidance on Modification to Compliance Policy

- Cigars
 - “Prioritize enforcement of “flavored” cigars that are “new tobacco products”
 - Enforcement is to be on a “case-by-case” basis
 - What is a “flavor”
 - Why not treat “flavored” cigars similarly to ENDS or menthol cigarettes

Draft Guidance on Modification to Compliance Policy

- Cigars
 - Youth Usage of cigars continues to decline in the face of the rising youth usage rates for e-cigarettes, and there is next to no youth usage of premium cigars



Proposed Rule on Content and Format of Substantial Equivalence Reports

- Same Characteristics – “so similar” scientific information is not needed
 - change in quantity;
 - change in container closure system;
 - decrease in total amount of tobacco w/o change in other ingredients/characteristics;
 - changes in non-combusted portion of a product, like adhesive
- Different Characteristics
 - change in filter/ventilation of combusted product;
 - change in container closure system for ST product (might impact stability/HPHC levels);
 - change in characterizing flavor, which might affect use behavior

Proposed Rule on Content and Format of Substantial Equivalence Reports

- Does a new product raise “different questions of public health”
 - The new product has the potential to increase HPHC yields, and if so, the degree of such an increase
 - The new product has the potential to increase toxicity
 - The new product has the potential to increase initiation
 - The new product has the potential to increase abuse liability
 - The new product has the potential to increase dependence
 - The new product has the potential to decrease cessation

Proposed Rule on Content and Format of Substantial Equivalence Reports

- Other considerations
 - Co-Packaging
 - Design Parameter Information
 - HPHC Testing
 - Stability Testing



Combustible Tobacco: Unfinished Business

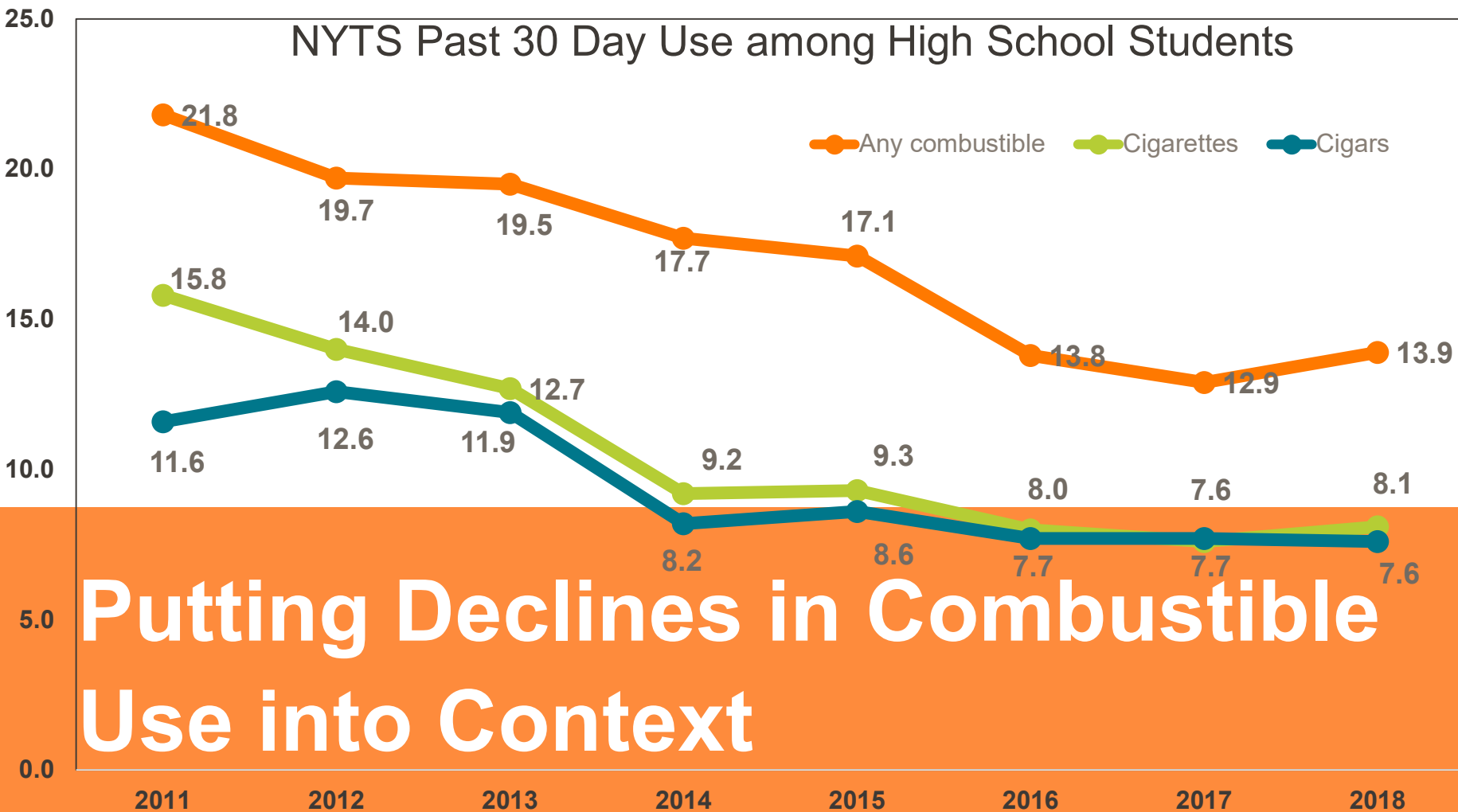
Stacey Younger Gagosian
Managing Director, Public Policy

Food and Drug Law Institute Annual Conference

May 2, 2019

NYTS Past 30 Day Use among High School Students

Any combustible Cigarettes Cigars

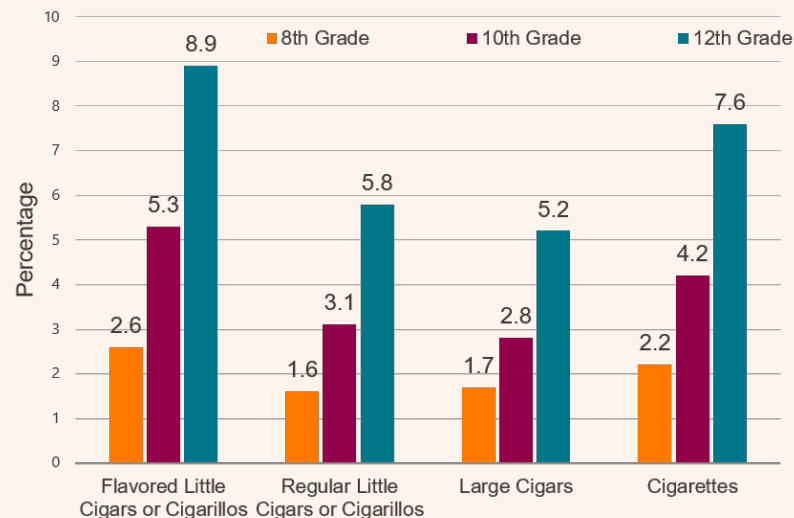


Putting Declines in Combustible Use into Context

Cigar Smoking Is a Problem

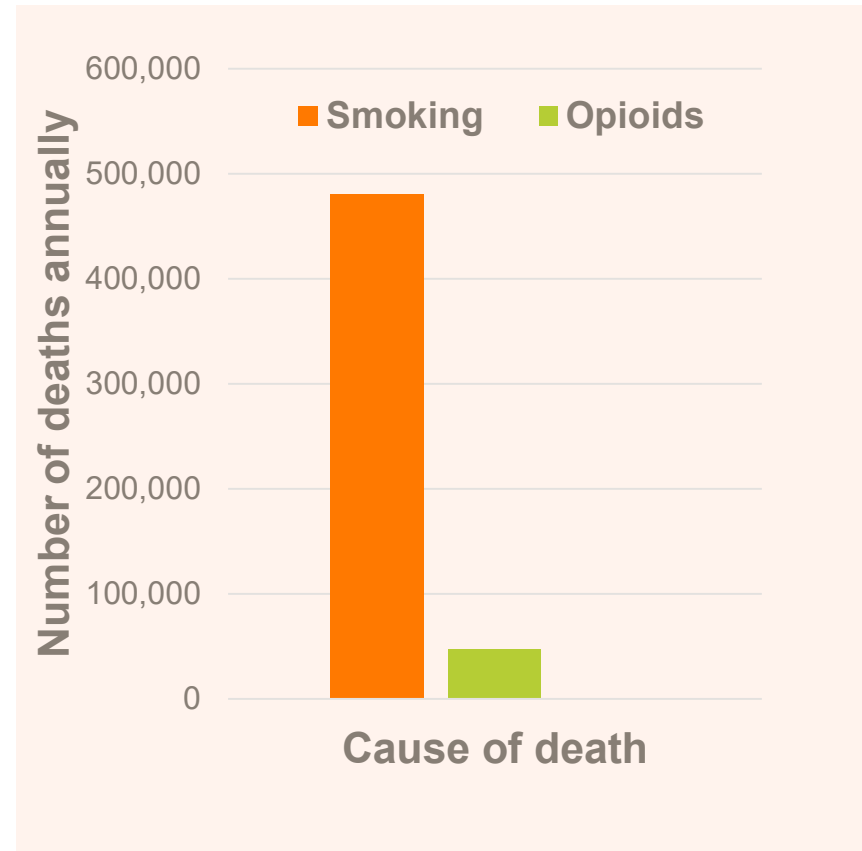
- 9,000 premature deaths caused by cigar smoking in 2012
- Consumers believe cigar smoking to be less harmful and more socially acceptable than cigarette smoking.
- The cigar market is heavily flavored and flavored cigar use is especially high among youth.
- Tobacco industry advertising and promotional activities of cigar products is associated with youth and young adult smoking initiation.

30-Day Prevalence of Combustible Tobacco Products Among Youth Monitoring the Future, 2018



Cigarette Smoking = Major Problem

- The burden of death and disease from tobacco use in the United States is overwhelmingly caused by cigarettes and other combusted tobacco products.
 - Smoking accounts for **480,000** deaths annually in the U.S.
 - ~1,300 smoking-related deaths per day
 - **5.6 million** of today's youth expected to die prematurely from smoking

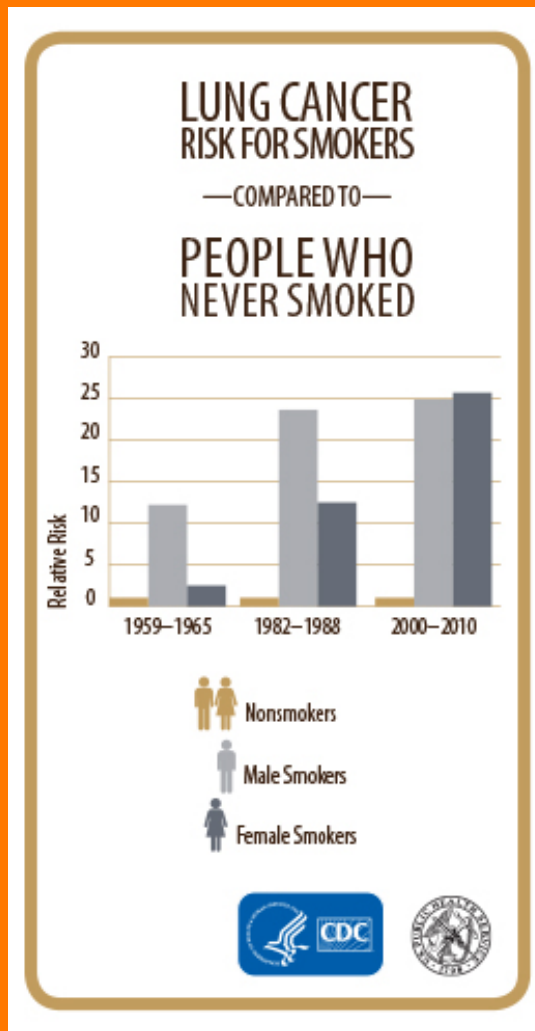


Cigarette Smoking = Major Problem

Cigarettes have become more lethal over time

- More death and disease, despite lower per capita consumption and lower smoking prevalence

U.S. Department of Health and Human Services. The Health Consequences of Smoking—50 Years of Progress. A Report of the Surgeon General. January 2014.

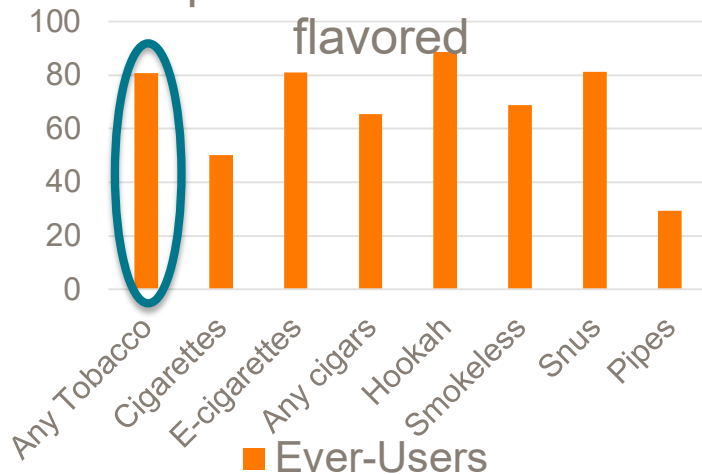




Flavored Tobacco

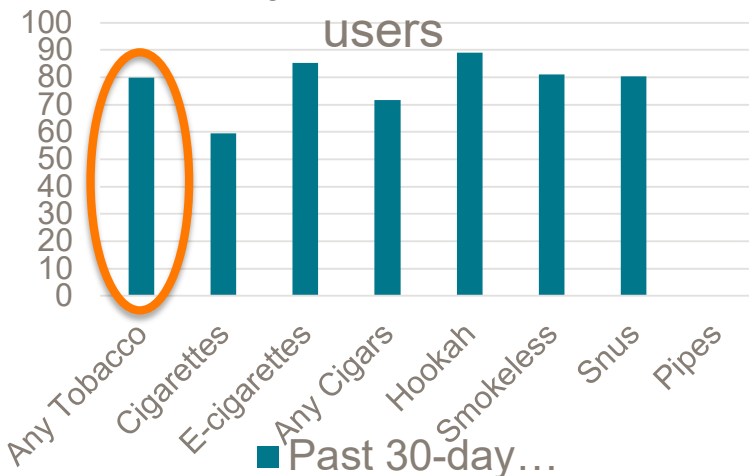
Flavored Tobacco

Proportion of youth ever users reporting first product used was



80% used flavored products

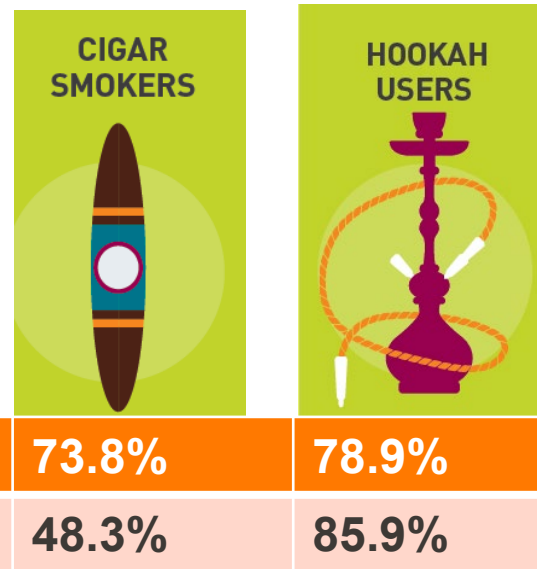
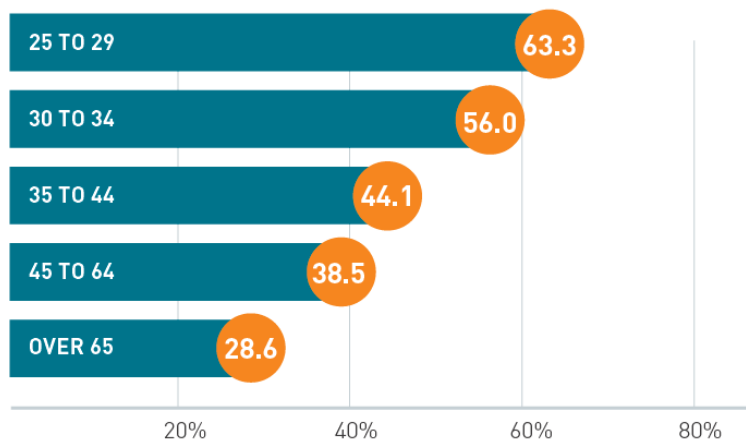
Proportion of Flavored tobacco use among Past 30-day Youth Tobacco users



79.8% used flavored products

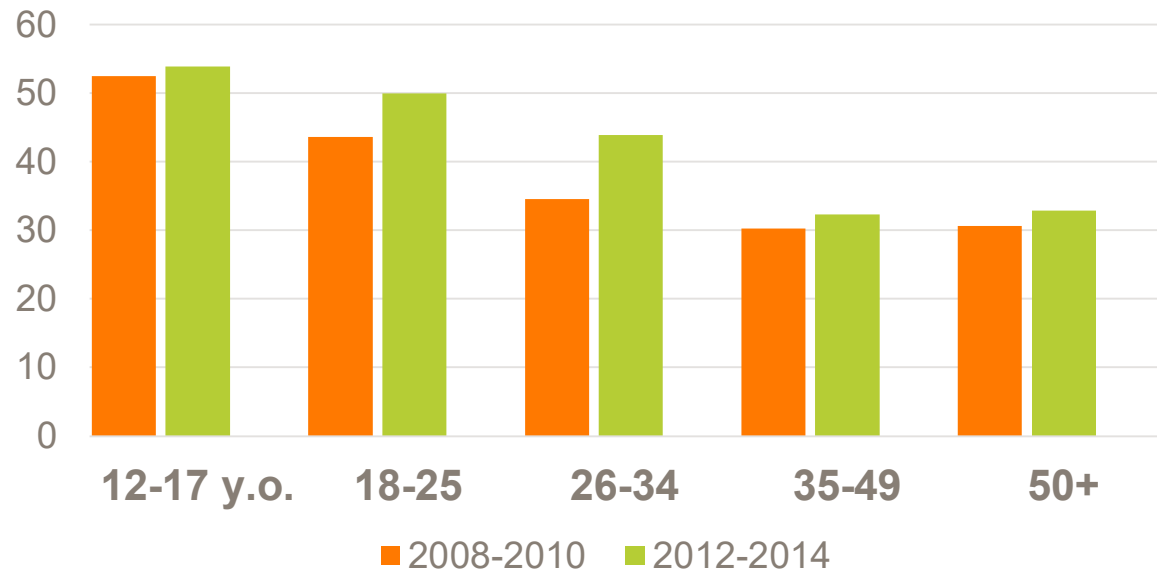
Youth and Young Adults Prefer Flavored Tobacco

Ages of Adult Tobacco Users Who Use Flavored Products⁹



Youth and Young Adults are More Likely to Use Menthol

Adjusted prevalence of use of menthol cigarettes among past 30-day smokers – United States, 2008-2010 and 2012-2014



Menthol Prevalence Increasing

- Non-menthol cigarette use declined in all age groups from 2004-2014
- Menthol cigarette use increased in young adults ages 18-25 during this time.
- More youth smoke menthols than non-menthols. Adults 26+ and over have not decreased their menthol use

Menthol vs. non-menthol smoking rates by age, 2004-2014

Youth (12-17 years old)



Young adults (18-25 years old)



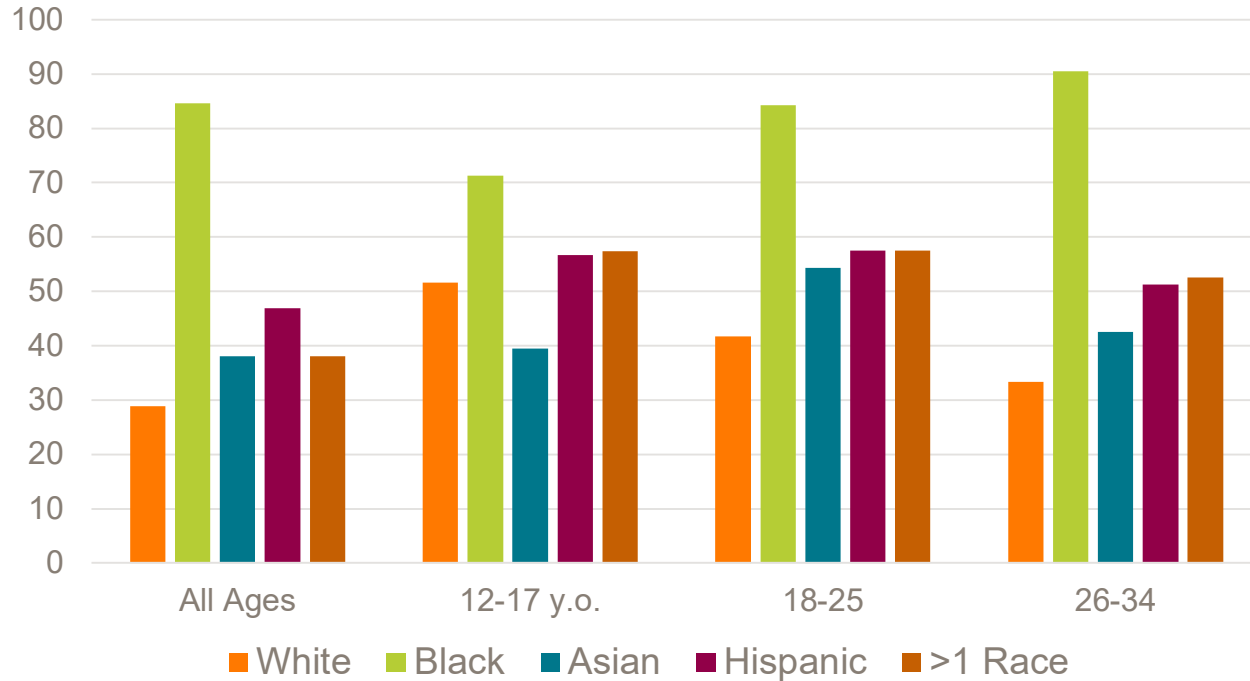
Adults (26+ years old)



Source: National Survey on Drug Use and Health, 2004-2014.

Menthol use is high among many minorities

Prevalence of Past-30 day Menthol Use by Race/Ethnicity 2012-2014



Menthol Cigarettes Impact Public Health

Increase
Initiation

- Youngest smokers use menthols at higher rates than older smokers

Increase
dependence

- Youth menthol smokers report higher levels of dependence
- Adult menthol smokers also show signs of higher dependence

Decrease
Cessation

- Menthol smokers are less successful in quitting

FDA Activity On Flavors/Menthol



FEDERAL REGISTER

The Daily Journal of the United States Government



FEDERAL REGISTER

The Daily Journal of the United States Government



PR Proposed Rule

PR Proposed Rule

Menthol in Cigarettes, Tobacco Products; Request for Comments

A Proposed Rule by the [Food and Drug Administration](#) on 07/24/2013

Regulation of Flavors in Tobacco Products

A Proposed Rule by the [Food and Drug Administration](#) on 03/21/2018

PUBLISHED DOCUMENT

AGENCY:

Food and Drug Administration, HHS.

ACTION:

Advance notice of proposed rulemaking.

SUMMARY:

The Food and Drug Administration (FDA) is issuing this advance notice of proposed rulemaking (ANPRM) to obtain information related to the potential regulation of menthol in cigarettes. FDA is also making available its preliminary scientific evaluation of public health issues related to the use of menthol in cigarettes. The preliminary scientific evaluation indicates there is likely a public health impact of menthol in cigarettes. This ANPRM is seeking comments, including comments on FDA's preliminary evaluation, and data, research, or other information that may inform regulatory actions FDA might take with respect to menthol in cigarettes.

DOCUMENT DETAILS

Printed version:

[PDF](#)

Publication Date:

07/24/2013

Agencies:

[Food and Drug Administration](#)

Dates:

Submit either electronic or written comments by September 23, 2013.

Comments Close:

09/23/2013

Document Type:

Proposed Rule

Document Citation:

78 FR 44484

Page:

44484-44485 (2 pages)

CFR:

21 CFR 1110

PUBLISHED DOCUMENT

AGENCY:

Food and Drug Administration, HHS.

ACTION:

Advance notice of proposed rulemaking.

SUMMARY:

The Food and Drug Administration (FDA) is issuing this advance notice of proposed rulemaking (ANPRM) to obtain information related to the role that flavors play in tobacco products. Specifically, this ANPRM is seeking comments, data, research results, or other information about, among other things, how flavors attract youth to initiate tobacco product use and about whether and how certain flavors may help adult cigarette smokers reduce cigarette use and switch to potentially less harmful products. FDA is seeking this information to inform regulatory actions FDA might take with respect to tobacco products with flavors, under the Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act). Potential regulatory actions include, but are not limited to, tobacco product

DOCUMENT DETAILS

Printed version:

[PDF](#)

Publication Date:

03/21/2018

Agencies:

[Food and Drug Administration](#)

Dates:

Submit either electronic or written comments by June 19, 2018.

Comments Close:

06/19/2018

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Document Citation:

83 FR 12294

Page:

12294-12301 (8 pages)

CFR:

21 CFR 1100

21 CFR 1140

21 CFR 1143

Agency/Docket Number:

Reduced Nicotine Combustible Tobacco

Reducing Nicotine will Improve Public Health

Nicotine is the reason people smoke combustible tobacco

- Industry manipulated levels of nicotine and added other ingredients to enhance addictiveness
- “Defendants have designed their cigarettes to precisely control nicotine delivery levels and provide doses of nicotine sufficient to create and sustain addiction”
 - Judge Judith Kessler

Youth and Young Adults are more vulnerable to nicotine addiction

- The earlier one is exposed to nicotine, the harder it is to quit
- 87% of smokers begin before the age of 18

Reducing Nicotine will Improve Public Health

Preventing youth and young adults from becoming addicted to combustible tobacco

- Those who experiment with combustible tobacco less likely to progress to regular use

Smokers encouraged to quit

- Removes the incentive to smoke
- Potential to reduce second hand smoke exposure

Studies show VLNCs reduce the number of cigarettes per day and increase cessation

Public Health Recommendations

1. Apply reduced nicotine product standard to all combustible tobacco products
 - Youth and young adults already use more than one product – so switching to higher nicotine products isn't a stretch for them
 - Industry adapts products to avoid regulation
2. Implementation must be all at once - not phased in
3. Education that reduced nicotine products are not safer
 - Less addictive, but still have many of the same toxins as cigarettes
4. Cannot be done on it's own – must be part of a comprehensive regulatory regime
 - Flavors; E-cigarette Regulation/Review

thank you

truthinitiative.org

