

# ***General Snus***

## **MRTP Renewal Tobacco Products Scientific Advisory Committee Meeting**

Swedish Match USA, Inc.

June 26, 2024

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# Introduction

**Gerry Roerty**

Vice President, Legal and General Counsel

# Modified Risk Products Under 911(g)(1)

**Section 911(g)(1)\* of the FD&C Act**  
**requires the applicant to demonstrate**  
**that the product and claim will:**



Significantly reduce harm  
and the risk of tobacco-related  
disease to individual  
tobacco users



Benefit the health of the population  
as a whole, taking into account both  
users of tobacco products and  
persons who do not currently use  
tobacco products

# FDA Authorized *General Snus* as Modified Risk

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- *General Snus*, when marketed with the modified risk claim, promotes complete switching and reduction in cigarettes
- *General Snus* does not appeal to youth

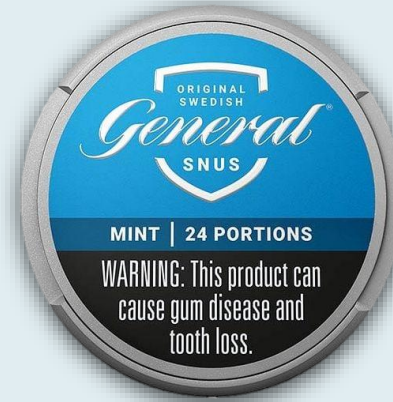
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- *General Snus* does not appeal to youth

**Real-world evidence and data, including PMSS,  
continues to demonstrate that *General Snus* is APPH**



# General Snus Products



# Authorized Modified Risk Information



“

Using *General Snus* instead of cigarettes puts you at a lower risk of mouth cancer, heart disease, lung cancer, stroke, emphysema, and chronic bronchitis.

”

# M RTP Renewal Guidance

## Guidance for Industry

### Modified Risk Tobacco Product Applications

#### DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Written comments and suggestions regarding this draft document may be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD, 20852. Alternatively, electronic comments may be submitted to <http://www.regulations.gov>. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft guidance, contact the Center for Tobacco Products at (Tel) 1-877-CTP-1373 (1-877-287-1373) Monday-Friday, 9:00 a.m. – 4:00 p.m. EDT.

Additional copies are available online at <http://www.fda.gov/TobaccoProductsGuidanceComplianceRegulatoryInformation/default.htm>. You may send an e-mail request to [SmallBiz.Tobacco@fda.hhs.gov](mailto:SmallBiz.Tobacco@fda.hhs.gov) to receive an electronic copy of this guidance. You may send a request for hard copies to U.S. Food and Drug Administration, Center for Tobacco Products, Attn: Office of Small Business Assistance, Document Control Center, Building 71, Room G335, 10903 New Hampshire Avenue, Silver Spring, MD 20993-0002.

U.S. Department of Health and Human Services  
Food and Drug Administration  
Center for Tobacco Products

March 2012








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1. FDA may renew an exposure modification order if the applicant files a new application and FDA finds that the requirements of such order under section 911(g)(1) continue to be satisfied.
2. When submitting an application for renewal of an order issued under section 911(g), you should ensure that you have complied with applicable requirements to provide results from the required postmarket surveillance and studies conducted pursuant to your order.








”

(emphasis added)

# PMTA and MRTP Pathways

	PMTA Pathway	MRTP Pathway
Benefit the health of the population on the whole (APPH)		
Postmarket surveillance		
Reduce harms and disease risks		
Modified risk claim		
Renewal process		

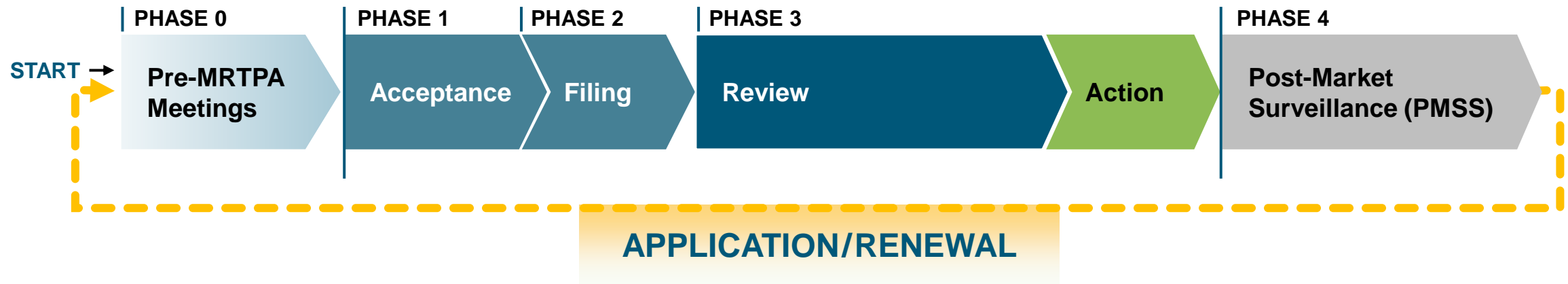
# PMTA and MRTP Pathways

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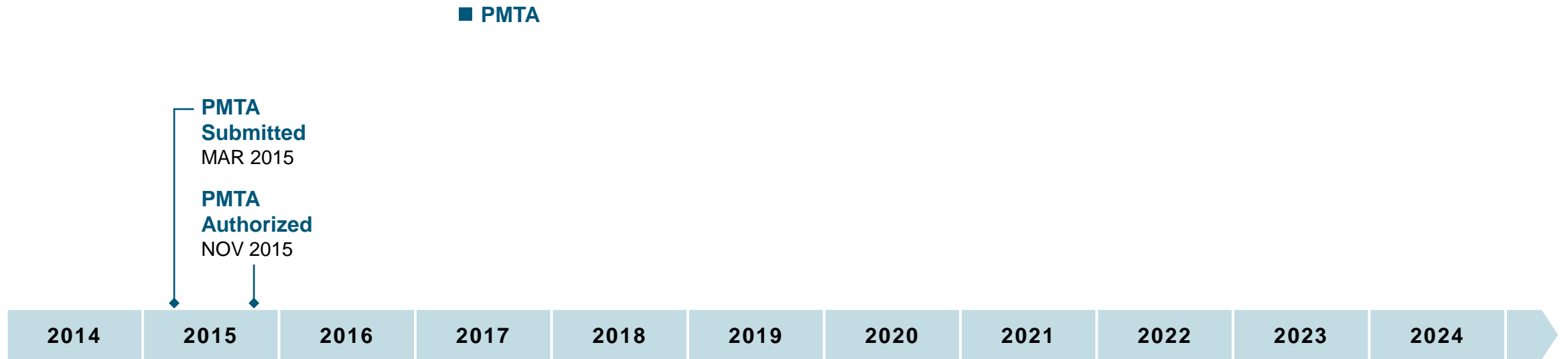
# Modified Risk Tobacco Product (MRTTP) Process



# Modified Risk Tobacco Product (MRTP) Process

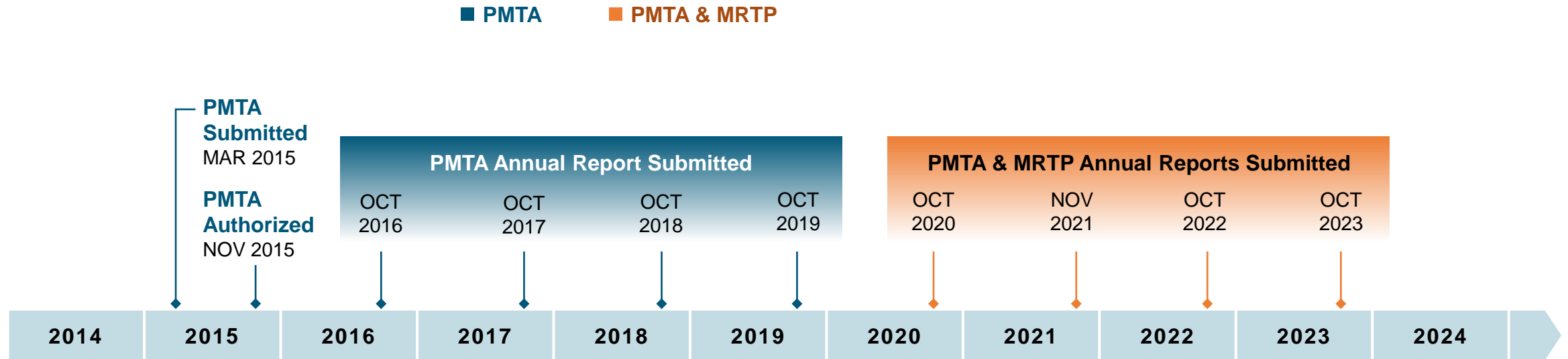


# Regulatory Timeline 2014–2024



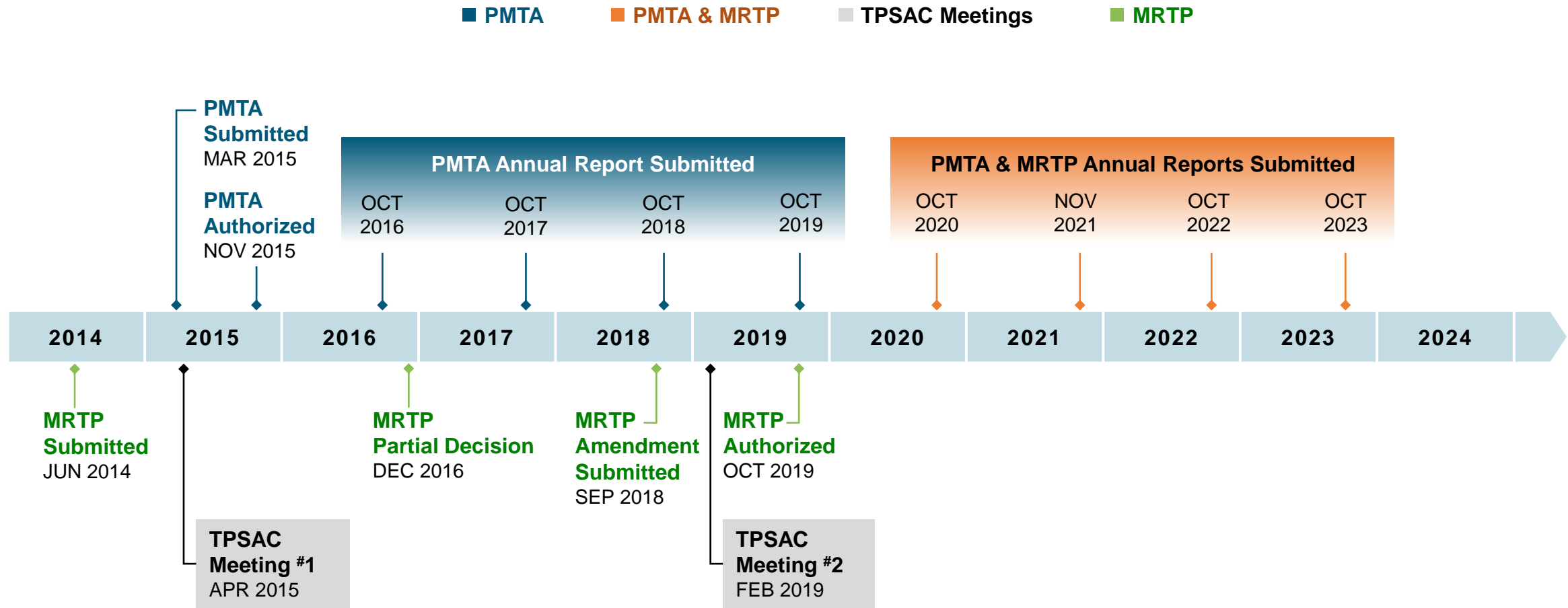


# Regulatory Timeline 2014–2024



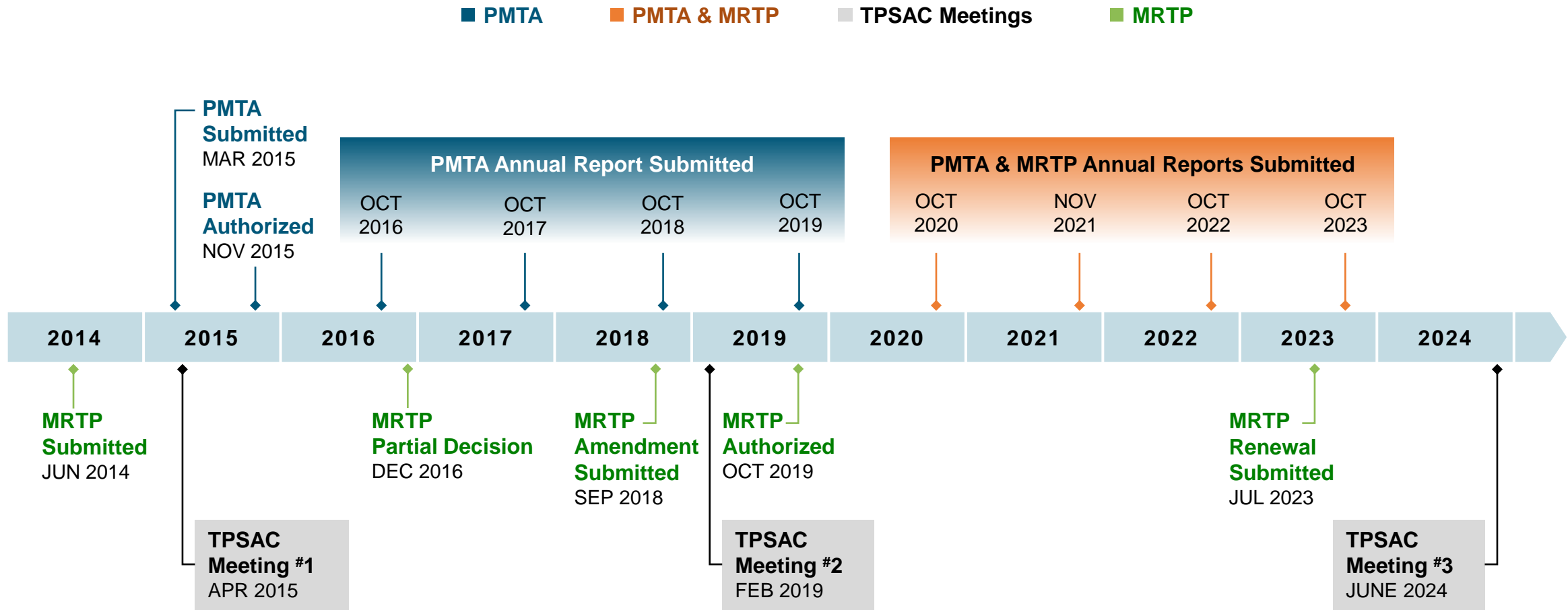
Note: Postmarket Surveillance and Studies (PMSS) Annual Reports, submitted since 2015 PMTA Authorization, provide requested information and data. We organized this presentation using these PMSS topics.

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# Postmarket Surveillance Supports FDA's Prior Authorizations

Prior evidence  
led to PMTA  
authorization

***General Snus***  
is APPH for  
both users  
and nonusers

Prior evidence  
led to MRTP  
authorization

***General Snus*** will  
significantly reduce  
harm and the risk of  
tobacco-related disease

Postmarket  
Surveillance and  
Studies (PMSS)

All PMSS and  
reporting  
requirements  
have been met

Products  
remain  
APPH

PMSS have not  
raised new  
questions of  
public health

**Real-world evidence and data, including PMSS,  
continues to demonstrate that *General Snus* is APPH**

# Areas of Assessment for MRTP Renewal



U.S. Food & Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993  
www.fda.gov

## Scientific Review of Modified Risk Tobacco Product Application (MRTPA) Under Section 911 (d) of the FD&C Act – Technical Project Lead

SUBMISSION INFORMATION			
Applicant	Swedish Match USA, Inc.		
Product Manufacturer	Swedish Match USA, Inc.		
Submission Date	June 10, 2014	FDA Receipt Date	June 10, 2014
Purpose	<input checked="" type="checkbox"/> Risk Modification (911(g)(1) order) <input type="checkbox"/> Exposure Modification (911(g)(2) order)		
Claims	Using General Snus instead of cigarettes puts you at a lower risk of mouth cancer, heart disease, lung cancer, stroke, emphysema, and chronic bronchitis.		
Primary STN(s)	MR0000020	General Loose	<input checked="" type="checkbox"/> Single <input type="checkbox"/> Co-Packaged Description: N/A
	MR0000021	General Dry Mint Portion Original Mini	<input checked="" type="checkbox"/> Single <input type="checkbox"/> Co-Packaged Description: N/A
	MR0000022	General Portion Original Large	<input checked="" type="checkbox"/> Single <input type="checkbox"/> Co-Packaged Description: N/A
	MR0000024	General Classic Blend Portion White Large – 12 ct	<input checked="" type="checkbox"/> Single <input type="checkbox"/> Co-Packaged Description: N/A
	MR0000025	General Mint Portion White Large	<input checked="" type="checkbox"/> Single <input type="checkbox"/> Co-Packaged Description: N/A
	MR0000027	General Nordic Mint Portion White Large – 12 ct	<input checked="" type="checkbox"/> Single <input type="checkbox"/> Co-Packaged Description: N/A
	MR0000028	General Portion White Large	<input checked="" type="checkbox"/> Single <input type="checkbox"/> Co-Packaged Description: N/A
	MR0000029	General Wintergreen Portion White Large	<input checked="" type="checkbox"/> Single <input type="checkbox"/> Co-Packaged Description: N/A

Amendments			
Amendment STN	Primary STN	Description	FDA Receipt Date
MR0000030	All	Market Tracker raw data	July 31, 2014
MR0000031	All	HPHC raw data	August 1, 2014
MR0000032	All	Background information related to cognitive testing for the premarket consumer perception study	August 5, 2014
MR0000033	All	Raw data for the consumer perception study	August 15, 2014
MR0000035	All	Response to November 12, 2014, FDA Information Request	December 3, 2014

1. Health risks to individual users
2. Consumer understanding and perceptions
3. Tobacco use behavior and impact to the population
4. Responsible marketing and controls

# Presentation Agenda

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## **Scientific Assessment of the MRTP**

- Health Risks to Individual Users
- Consumer Understanding and Perceptions
- Tobacco Use Behaviors and Impact to the Population

**Tryggve Ljung, MD, PhD**  
VP, Scientific Affairs

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## **Marketing Assessment of the MRTP**

- Responsible Marketing and Controls

**Jennifer Mulligan**  
Director, Marketing Services

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# Health Risks to Individual Users

**Dr. Tryggve Ljung, MD, PhD**

Vice President, Scientific Affairs

# FDA's Prior Conclusions

## Reductions in Harmful and Potentially Harmful Constituents (HPHCs)



### FDA's prior evaluation of HPHCs:

“

[T]he levels of NNN and NNK...in these *General Snus* products are lower than those in the vast majority of smokeless tobacco products on the U.S. market, and when used exclusively instead of other smokeless tobacco products, the *General Snus* products offer the potential for reductions in oral cancer risk.

”

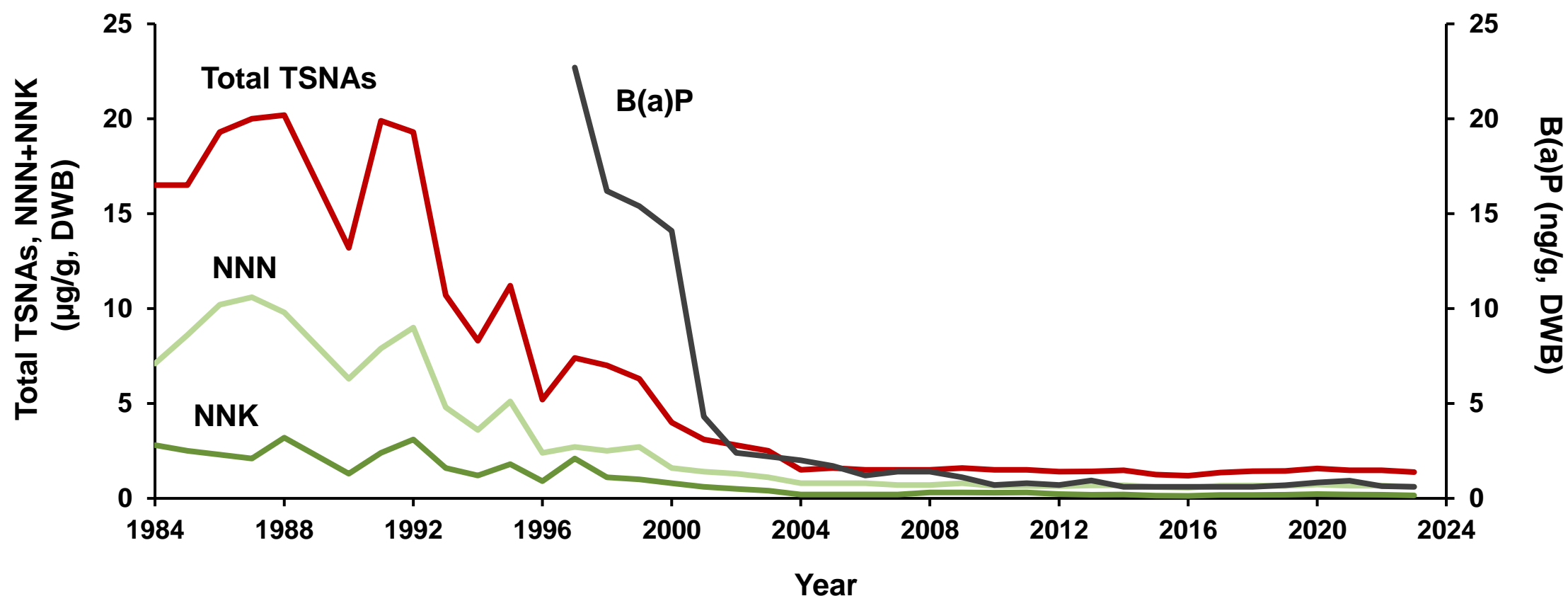
– *FDA 2019 MRTP TPL*



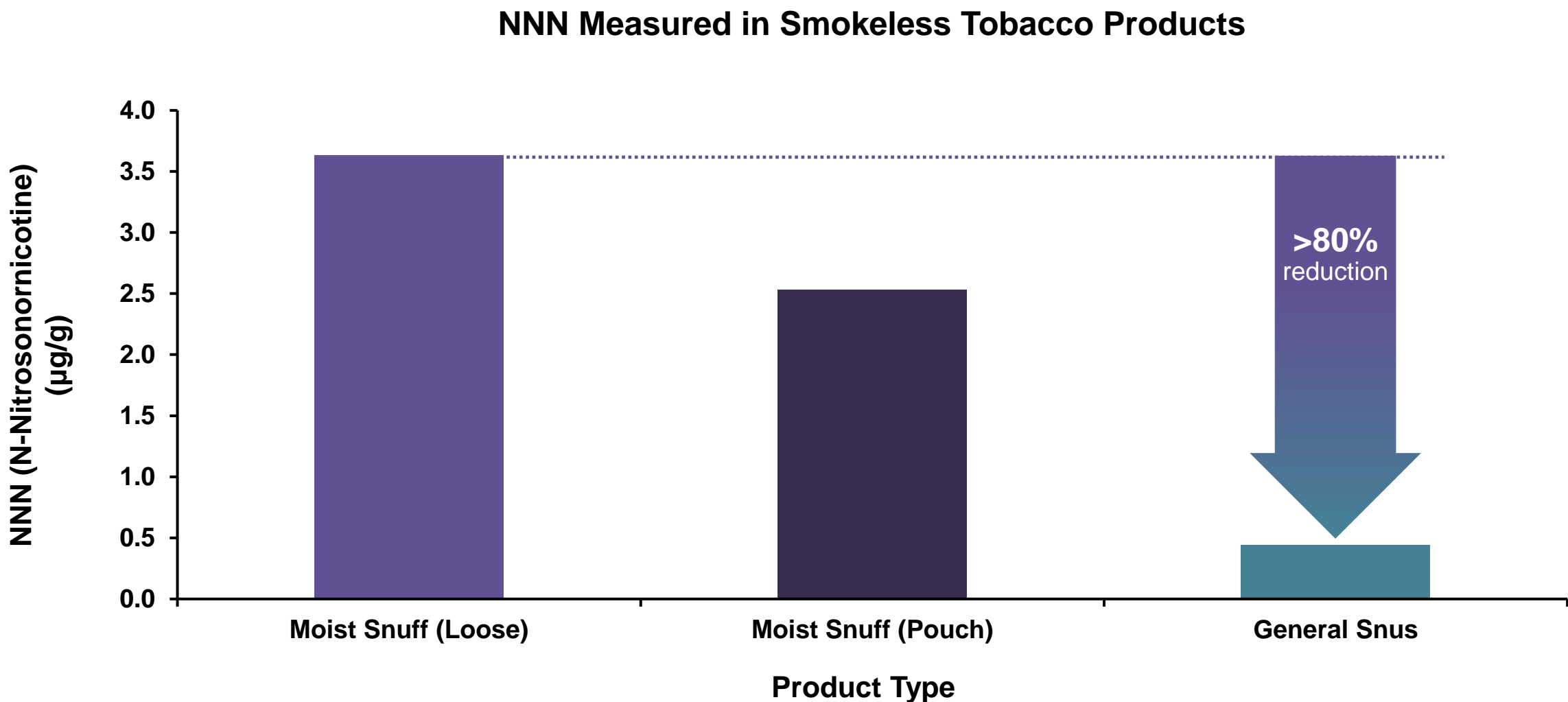
# HPHC Reductions Monitored by Gothiatek®

## GOTHIATEK® Has Contributed to Reduction in Harmful Constituents

Levels of NNN, NNK, B(a)P, and total TSNA's have been dramatically reduced



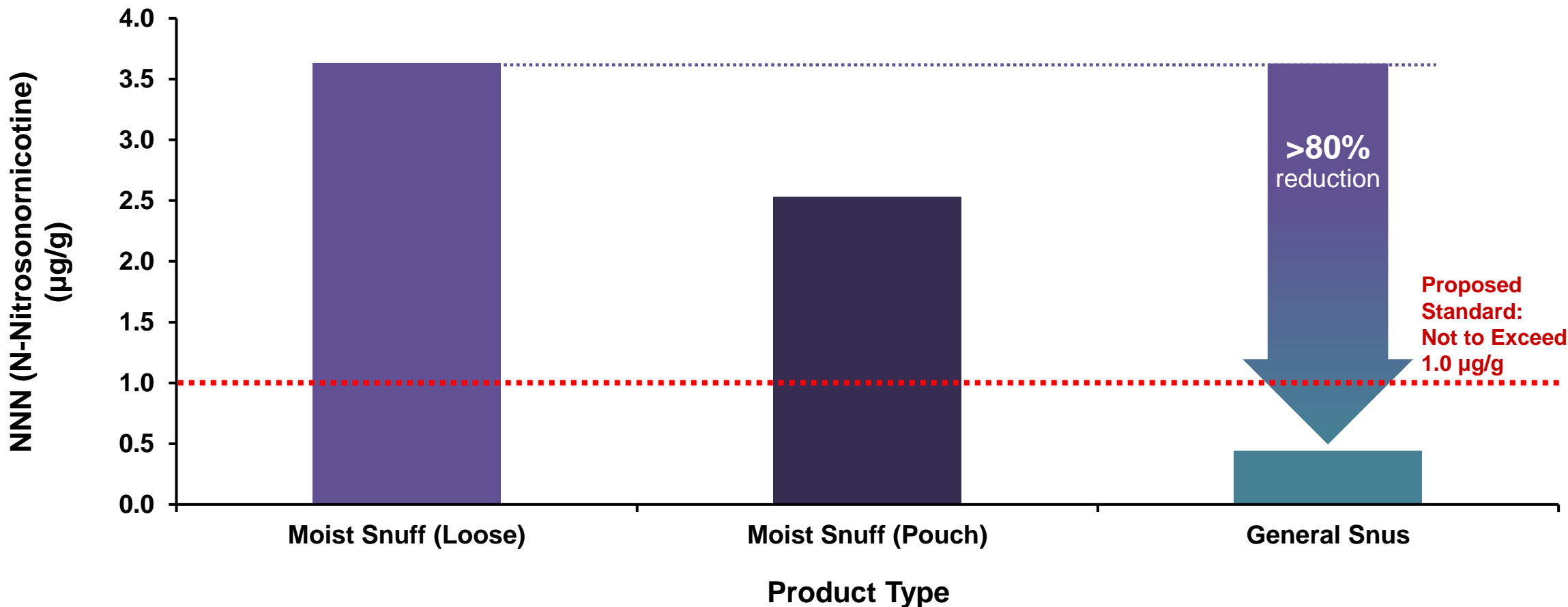
# General Snus Has Significantly Lower Levels of NNN



Source: Back S, Masser AE, Rutqvist LE, Lindholm J. Harmful and potentially harmful constituents (HPHCs) in two novel nicotine pouch products in comparison with regular smokeless tobacco products and pharmaceutical nicotine replacement therapy products (NRTs). BMC Chem. 2023 Mar 3;17(1):9.

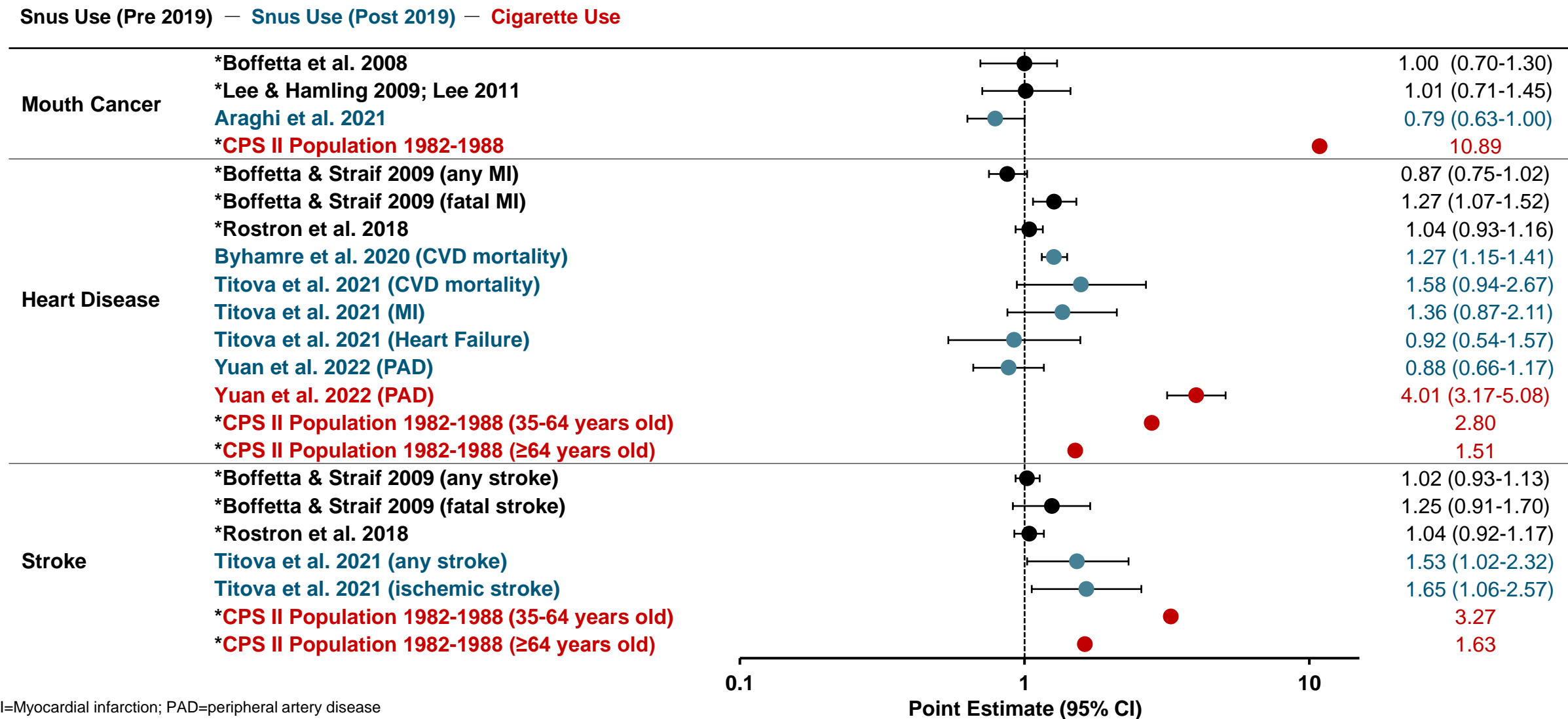
# General Snus Has Significantly Lower Levels of NNN

NNN Measured in Smokeless Tobacco Products



Source: Back S, Masser AE, Rutqvist LE, Lindholm J. Harmful and potentially harmful constituents (HPHCs) in two novel nicotine pouch products in comparison with regular smokeless tobacco products and pharmaceutical nicotine replacement therapy products (NRTs). BMC Chem. 2023 Mar 3;17(1):9.

# Epidemiology Demonstrates Reduced Risk of Tobacco-Related Diseases



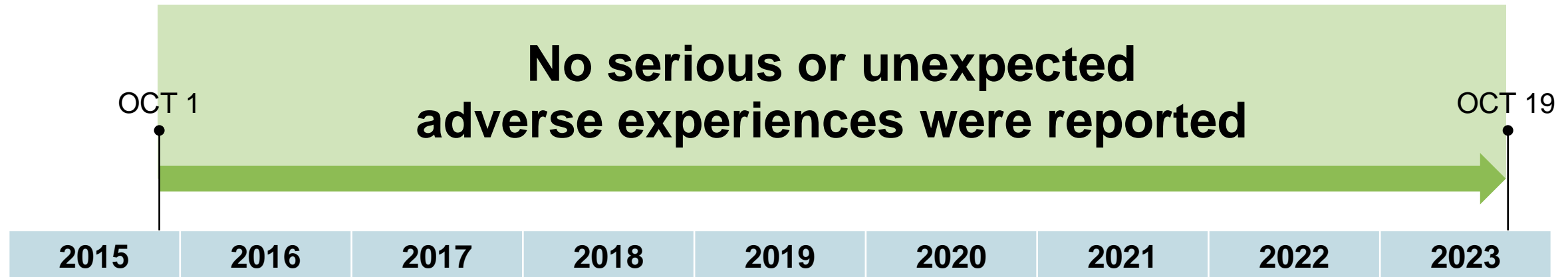
MI=Myocardial infarction; PAD=peripheral artery disease

\*Relative risk is used where Hazard Ratios were not available.

Premarket data based on the 2019 *General Snus* TPSAC meeting materials. CPS II by the American Cancer Society used for comparison purposes only.

# No Reported Serious or Unexpected Adverse Experiences (AEs) in the U.S. or Internationally

**Throughout the postmarket surveillance period**  
(for both PMTA and MRTP authorizations)  
Oct. 1, 2015 to Oct. 19, 2023



**Ongoing monitoring does not signal any concerns regarding AEs related to product use**

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# **Consumer Understanding and Perceptions**

# FDA's Prior Conclusions

## Comprehension of Relative Risk of *General Snus* Compared to Cigarettes



“

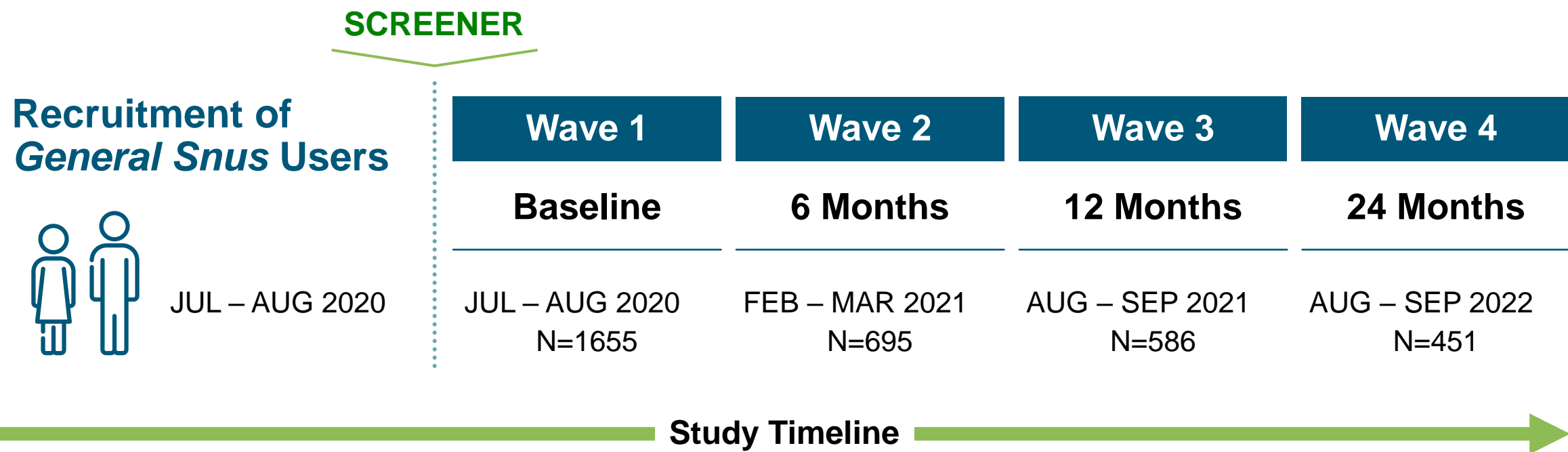
Overall, these results provide evidence that **consumers generally understood the proposed modified risk claim** and the health risks of using [*General Snus*] in the context of total health. Exposure to the claim led to consumers understanding that the **relative risk of snus is lower compared to smoking** with respect to the health outcomes described in the claim.

”

– *FDA 2019 MRTP TPL*  
(emphasis added)

# Experimental Design

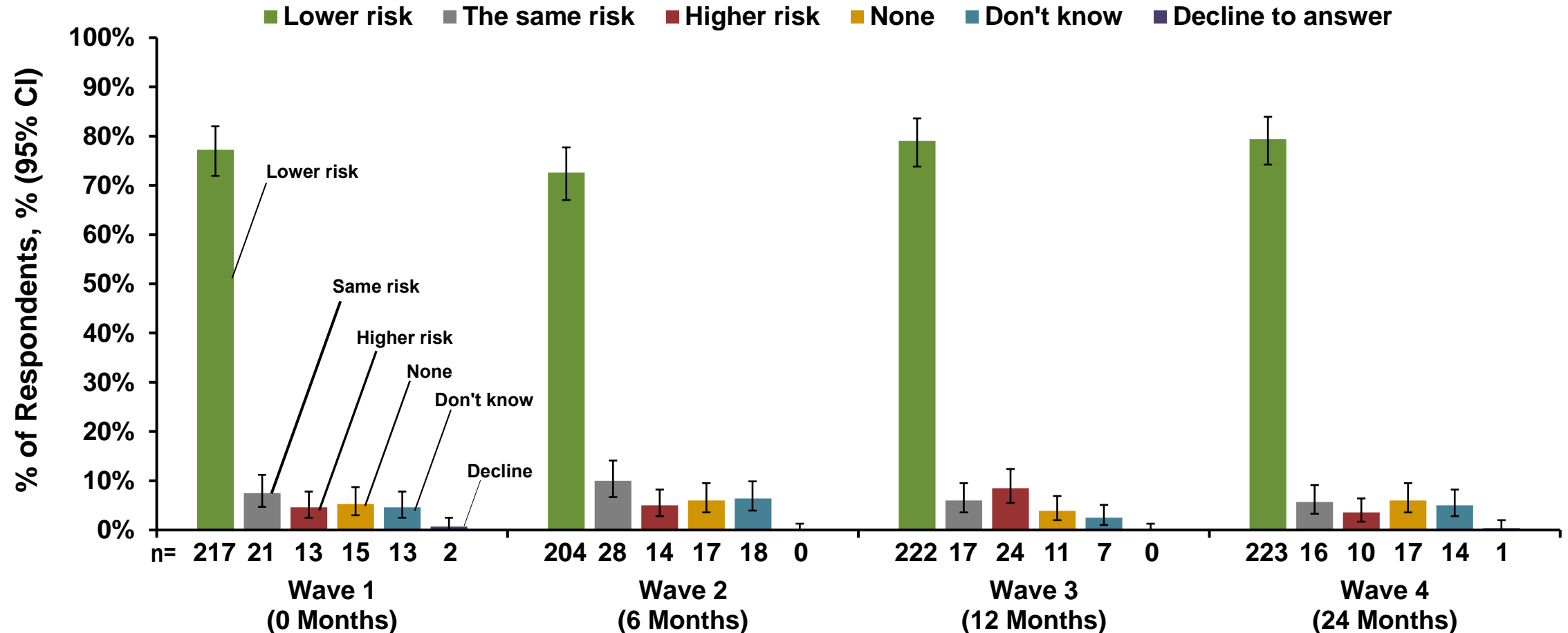
## General Snus Patterns of Use (POU) Study





# Respondents Overwhelmingly Comprehend Relative Risk of Using *General Snus* Instead of Smoking Cigarettes

## Reported Disease Risks Associated with Using *General Snus* Instead of Cigarettes



Source: *General Snus* POU Study. This analysis was conducted using data from the 281 participants who completed all four waves. Question: Using *General Snus* instead of cigarettes.... Puts you at lower risk for mouth cancer, heart disease, lung cancer, stroke, emphysema, and chronic bronchitis. OR Does not affect your risk for mouth cancer, heart disease, lung cancer, stroke, emphysema, and chronic bronchitis. OR Puts you at higher risk for mouth cancer, heart disease, lung cancer, stroke, emphysema, and chronic bronchitis. OR None of the above, Don't know, Decline to answer.

# FDA's Prior Conclusions

## Respondents Understand the Need to Completely Switch



“

[T]he proposed claim did *not* lead smokers to believe that partial substitution would reduce their disease risk.

[T]he proposed claim enabled consumers to understand that dual use of *General Snus* with cigarettes is more harmful than exclusively using *General Snus*.

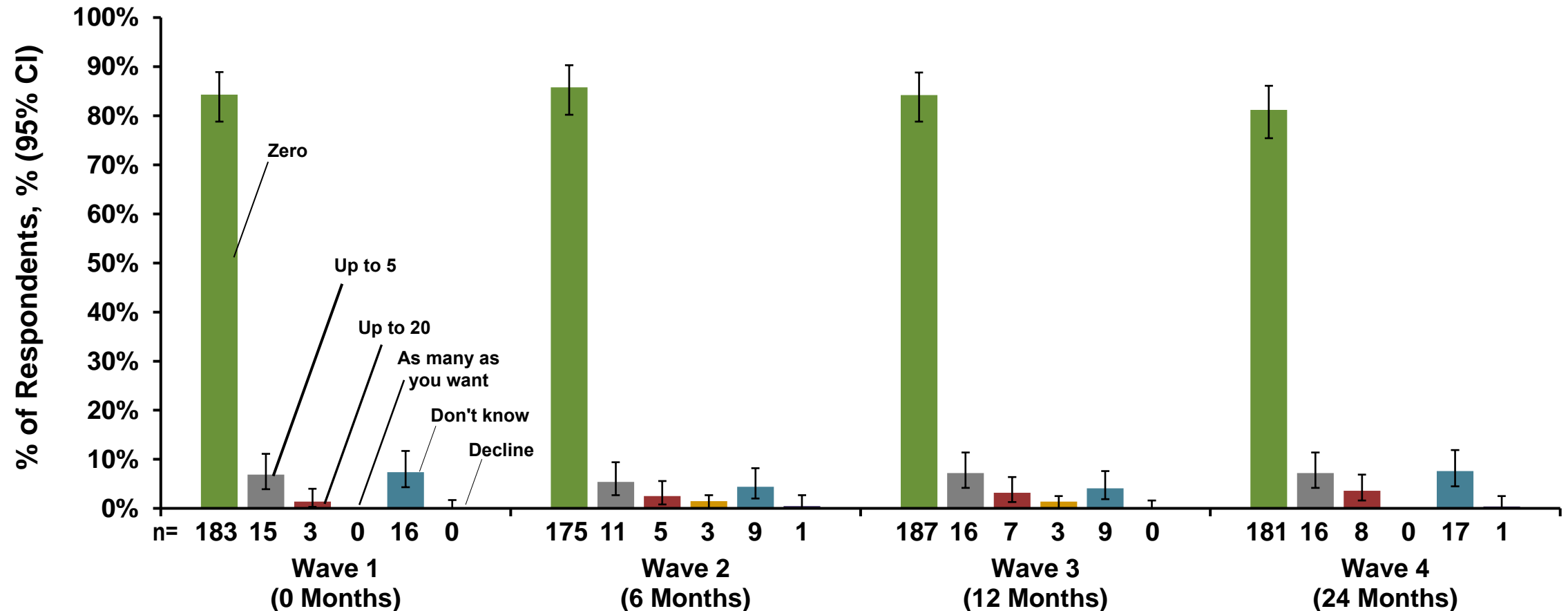
”

– *FDA 2019 MRTP TPL*

# Respondents Overwhelmingly Understand Need to Completely Switch to Maintain a Lower Risk of Disease

How many cigarettes can be smoked in addition to using *General Snus* to maintain a lower risk of diseases?

■ Zero cigarettes ■ Up to 5 cigarettes ■ Up to 20 cigarettes ■ As many as you want to smoke ■ Don't know ■ Decline to answer



Source: *General Snus* POU Study. This analysis was conducted using data from the 281 participants who completed all four waves. The question was asked of only those respondents who correctly identified that using *General Snus* instead of cigarettes puts you at a lower risk of disease. Question: "You said that using *General Snus* instead of cigarettes puts you at lower risk of diseases. If you are going to use *General Snus* instead of cigarettes to lower your risk of diseases, how many cigarettes, if any, can you smoke per day?"

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# **Tobacco Use Behavior and Impact to the Population**

# FDA's Prior Conclusions

Switching and Reduction in Cigarettes Per Day (CPD) Among *General Snus* Users



**FDA's prior conclusion on switching to *General Snus*:**

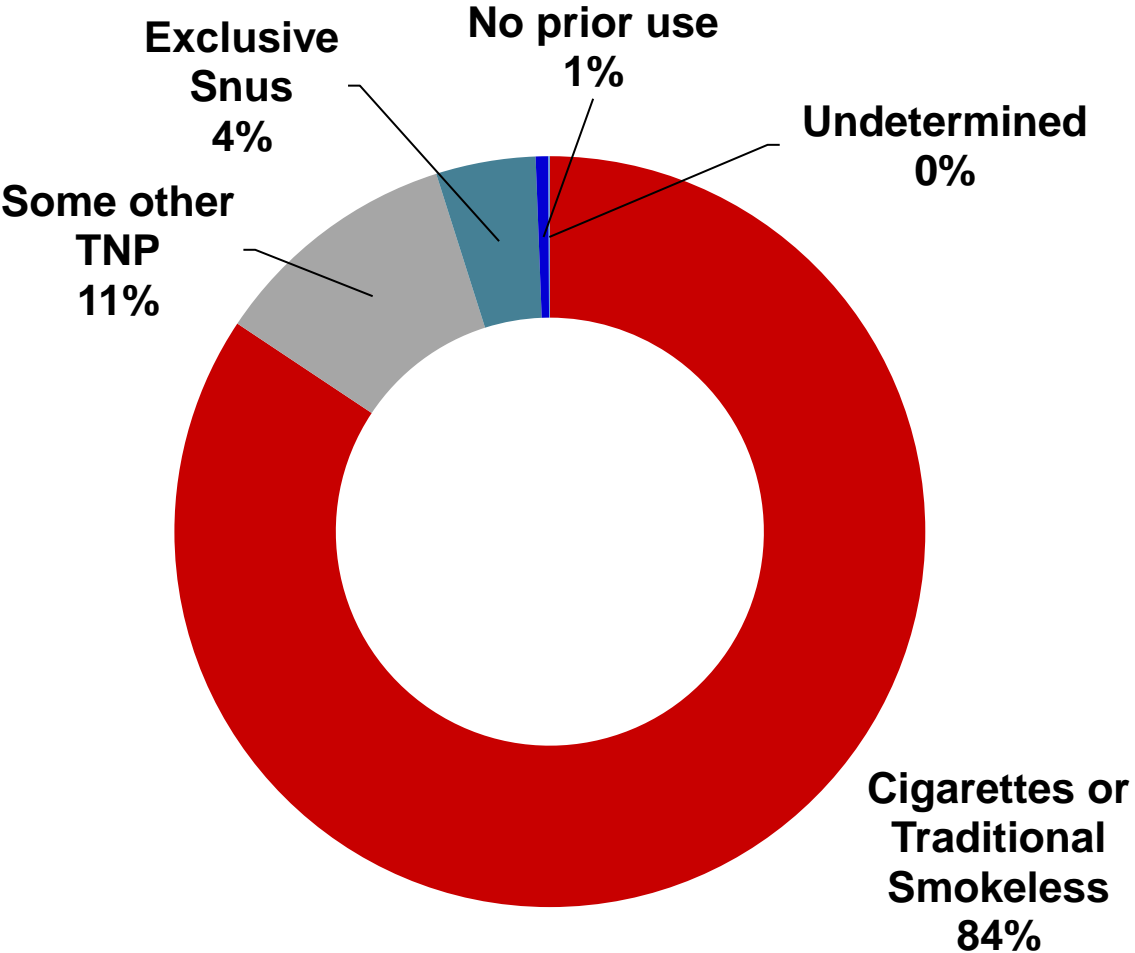
“

the MRTPs' marketing [is] expected to result in a population health benefit [for] **smokers completely switching to snus** use. In addition ... evidence suggests that, **compared to exclusive use of other smokeless tobacco products**, exclusive use of these snus products pose reduced exposure to some HPHCs and offer the potential for reductions in oral cancer risk.

”

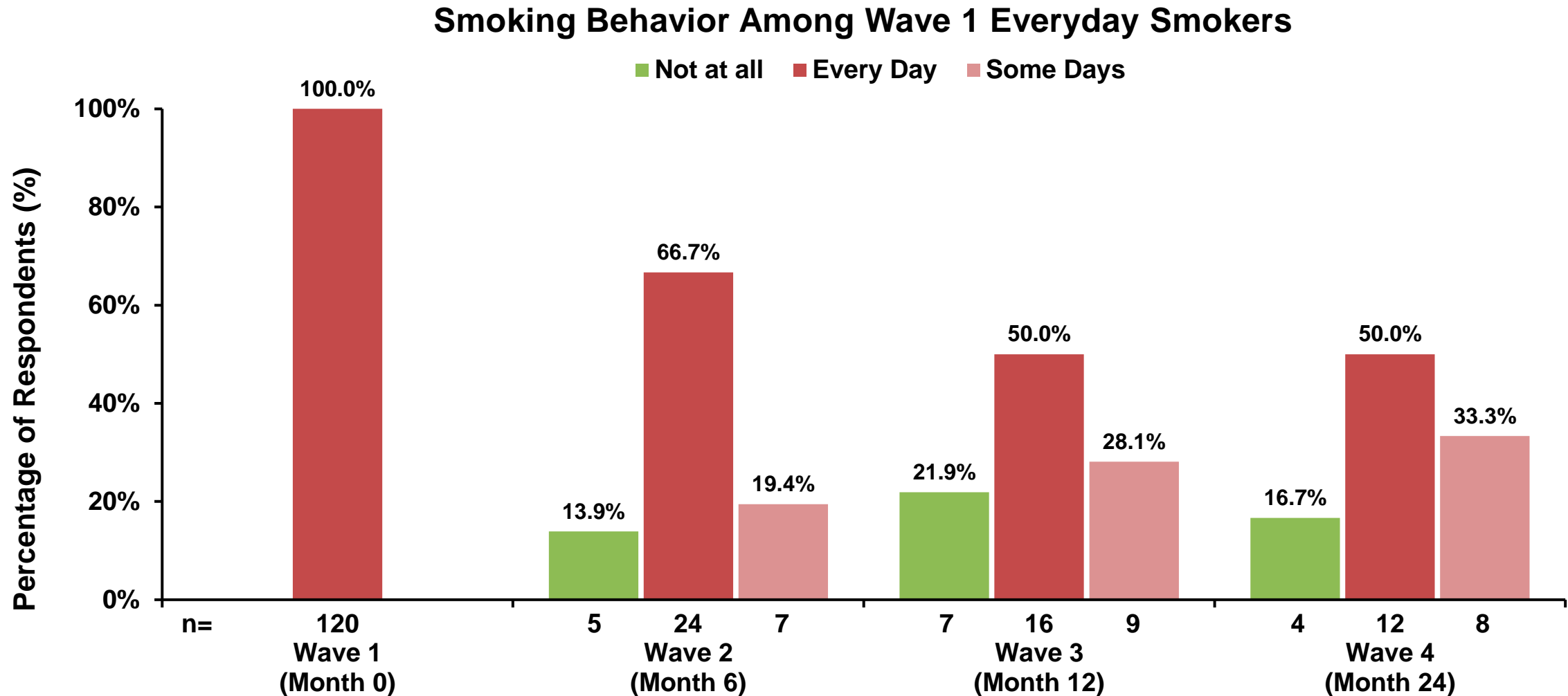
– *FDA 2019 MRTP TPL*  
(emphasis added)

# Established *General Snus* Users Report Prior Fairly Regular Use of TNPs



Source: *General Snus* POU Study. Question: Have you ever used any of the following tobacco or nicotine products fairly regularly? 1- Cigarettes, 2 - E-cigarettes, 3 - Moist snuff (available in loose form, also known as dip, and in pouches), 4 - Chewing tobacco (also known as loose leaf chewing tobacco), 5 - Snus (pouch tobacco product, different than moist snuff), 6 - Nicotine pouches (tobacco-free pouch, placed in the mouth), 7 - Aids to help stop smoking (e.g. Nicorette, Nicoderm CQ), 8 - Cigars, cigarillos, filtered cigars filled with tobacco, 9 - Pipe tobacco, 10 - Hookah or water pipe tobacco.

# Switching Among *General Snus* Users

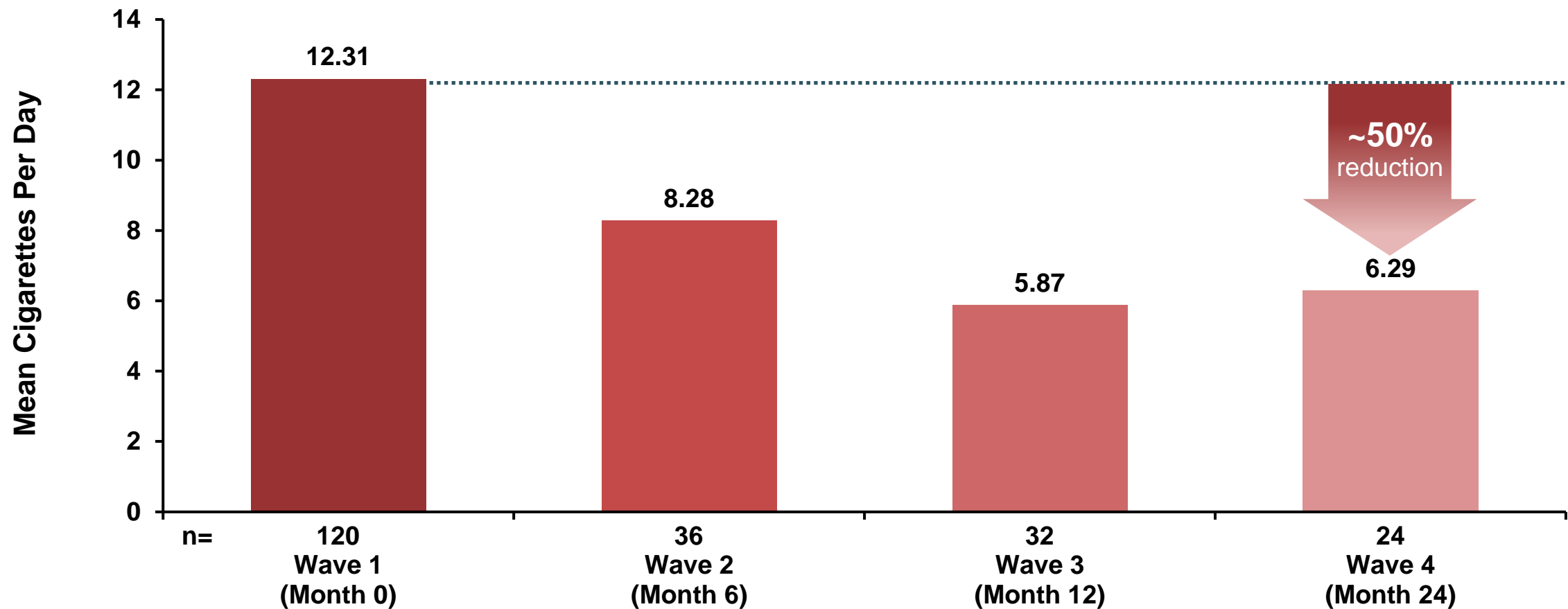


Source: *General Snus* POU Study

Question: In the past 30 days, how often did you use the following tobacco or nicotine products? 1 - Every Day, 2 - Some Days, 3 - Not at All, 4 - Don't Know.

# Reduction in CPD Among *General Snus* Users

Mean Cigarettes Per Day Among Wave 1 Everyday Smokers



Source: *General Snus* POU Study  
Question: On average, about how many cigarettes do you now smoke each day? A pack usually has 20 cigarettes in it. \_\_\_\_# of cigarettes per day [RANGE = 0-80]



# FDA's Prior Conclusions

## Snus is not a Product Category of Particular Interest to Youth



### FDA's prior conclusion on youth appeal and use:

“

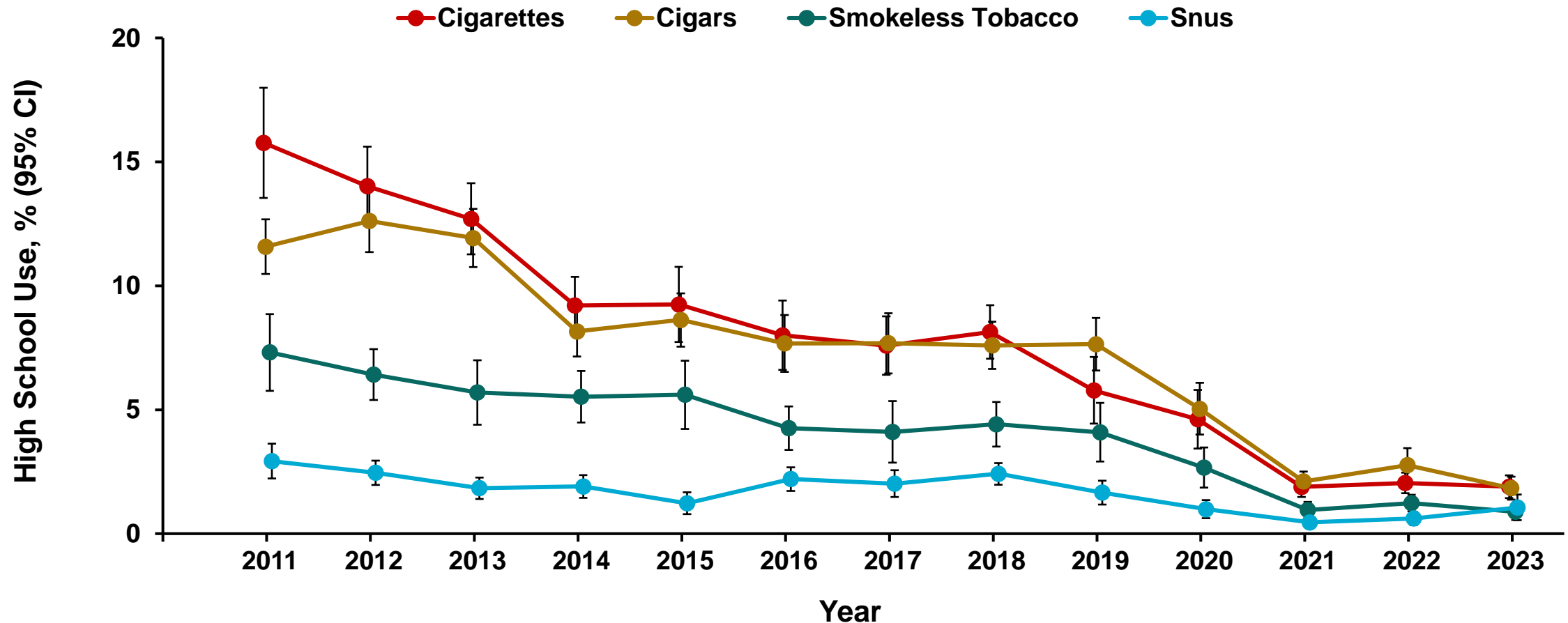
Although youth are, in general, at risk for tobacco use initiation, surveillance data on U.S. youth tobacco use suggest snus is not a product category of particular interest among youth.

”

– FDA 2019 MRTP TPL

# Consistently Low Prevalence of Youth Use (NYTS)

NYTS Estimates for Past 30-Day Use<sup>a</sup> of Traditional TNP, 2011–2023

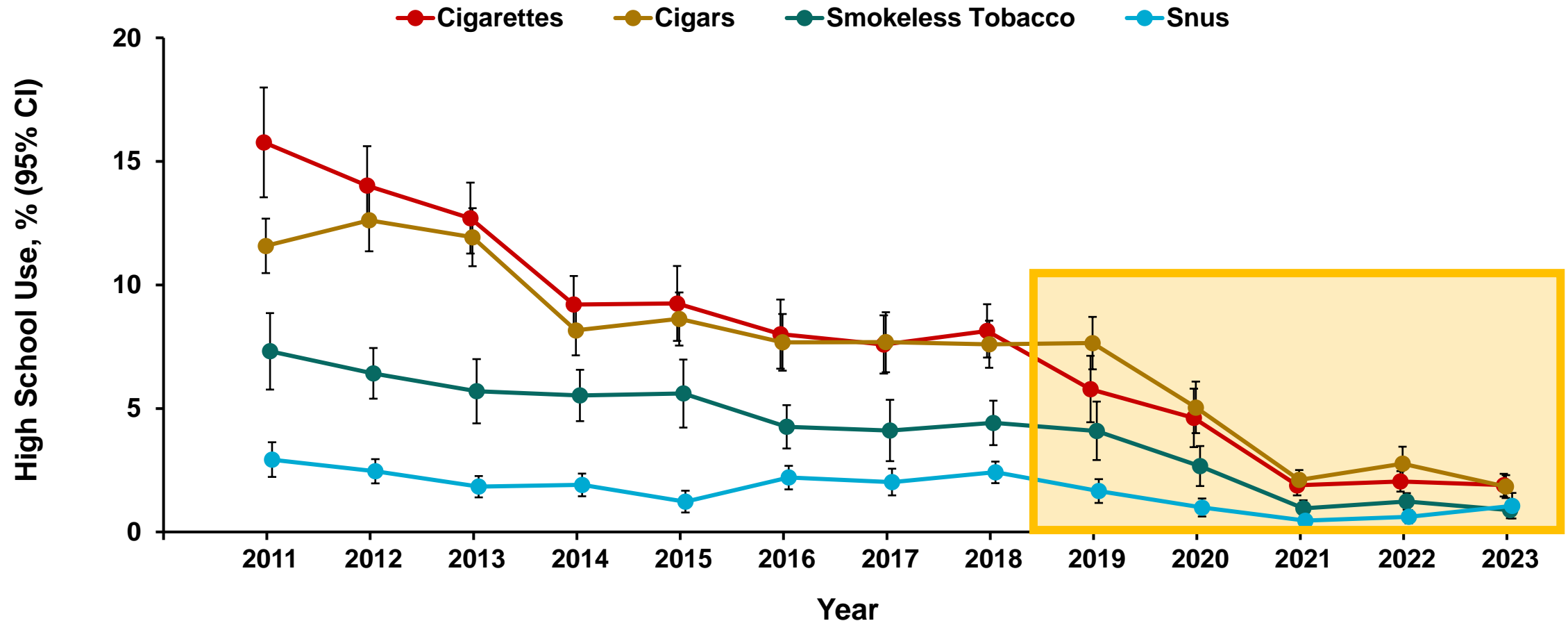


a. Current youth use of tobacco and nicotine products in NYTS is defined as use on 1 or more of the past 30 days.

National Youth Tobacco Survey (NYTS) is a nationally representative survey of middle and high school youth in the U.S. This survey is a collaboration between the Centers for Disease Control and Prevention, Office on Smoking Health (CDC, OSH) and the U.S. Food and Drug Administration, Center for Tobacco Products (FDA, CTP).

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# Conclusions From the Scientific Assessment

**No serious AEs were reported in the U.S. or internationally**

**Respondents in the POU study continue to understand:**

- The relative risk of *General Snus* use is lower than cigarettes
- The need to switch completely to *General Snus*

**Over the 24-month POU study:**

Of everyday smokers using *General Snus*:



**16.7%**  
completely  
stopped  
smoking

**33.3%**  
became  
someday  
smokers

**50%**  
reduction  
in CPD

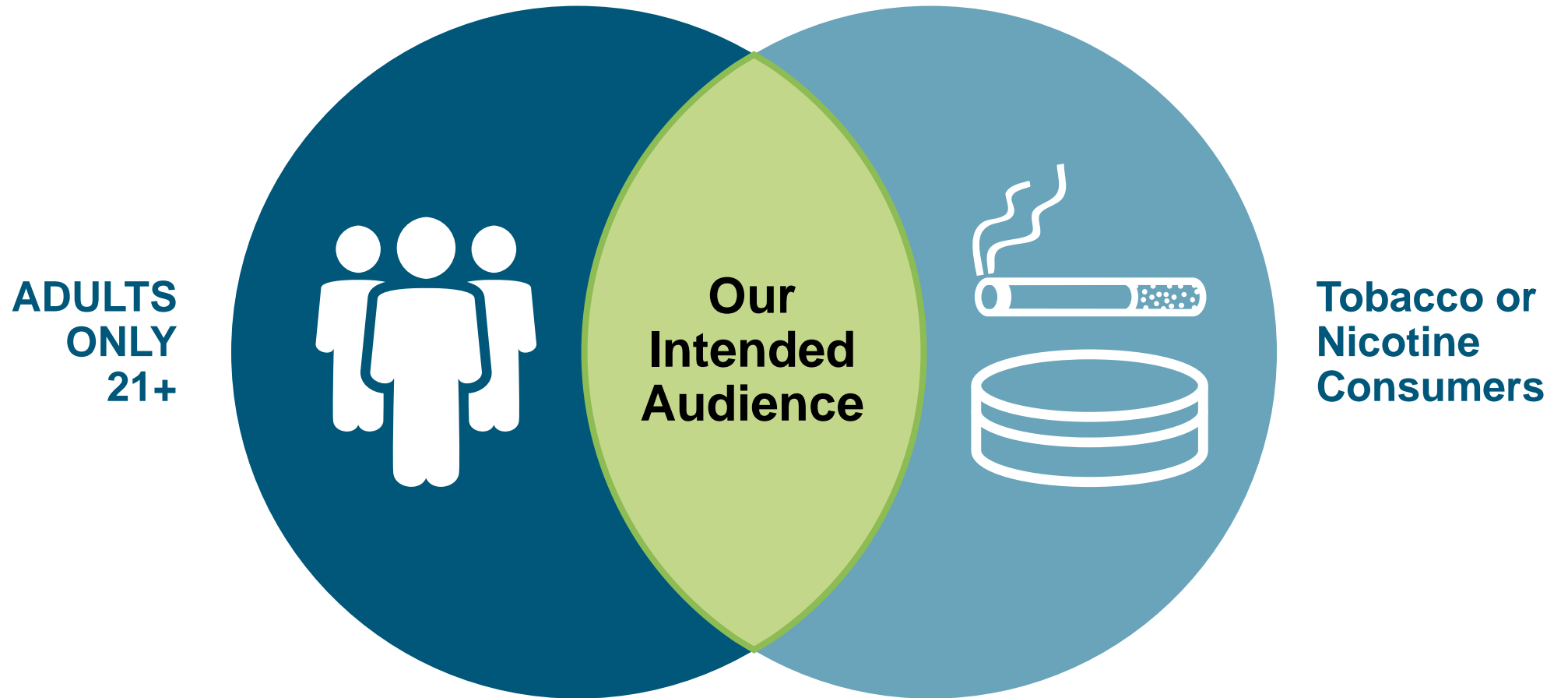
**Prevalence of use of snus in youth is approximately 1%**

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# Responsible Marketing and Controls

**Jen Mulligan**  
Director, Marketing Services

# Our Intended Audience



# FDA's Annual Reporting Requirements for Marketing

- ✓ Description of implementation of all advertising and marketing plans
- ✓ Targeting of specific adult audiences
- ✓ Actions taken to restrict youth access and limit youth exposure
- ✓ Use of owned, earned, shared/social, paid media, partners, influencers, bloggers, and/or brand ambassadors
- ✓ Consumer events, including events at which products are demonstrated
- ✓ Use of Public Relations outreach
- ✓ Analysis of actual delivery of advertising impressions
- ✓ Summary of media tracking and optimization

# Our Responsible Marketing Practices Exceed Those Required by the FDA and by Law

**Adherence to  
FDA-mandated marketing  
rules and regulations**

**Display of all required  
smokeless warnings,  
as applicable**

**Conservative  
marketing approaches  
to protect public health**



**Additional **VOLUNTARY** measures to ensure responsible marketing  
for our entire portfolio of tobacco and nicotine products**



# Responsible Marketing of Our Products

Proactive Transparency

**Transparency with  
both consumers  
and policymakers  
is invaluable**



# Responsible Marketing of Our Products

## Careful Retail Placement

**We require retailers to merchandise *General Snus* in non-self-serve locations unless the store is an adult-only facility**



# Responsible Marketing of Our Products

## Restraint with Advertising

***General Snus* does not advertise outdoors, or through TV and other mass media vehicles**



# Responsible Marketing of Our Products

## Restraint with Advertising

**All models/talent  
are visibly over  
the age of 35**



# Responsible Marketing of Our Products

## Restraint with Advertising

***General Snus* does not engage with consumers on social media platforms that are not age-restricted**





# Responsible Marketing of Our Products

## Restraint with Advertising

***General Snus* does not use paid professional athlete endorsements/sponsorships, or social influencers in our marketing**

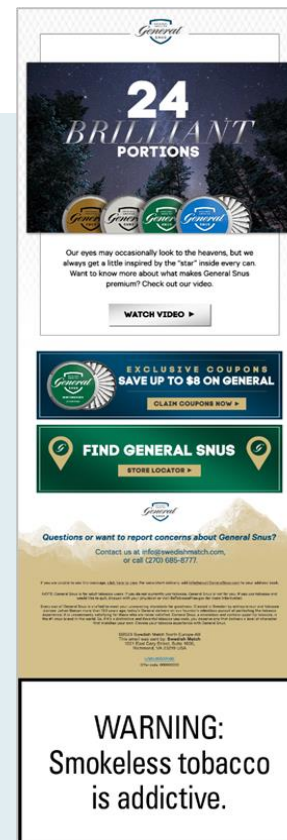


# Examples of Marketing Materials

## Point-of-Sale Marketing



## Email to Age-Verified Consumers



## Direct Mailer to Age-Verified Consumers



# Responsible Marketing of Our Products

## Age-Gated Website

### Consumers must successfully:

- ✓ Verify their age
- ✓ Confirm they are current tobacco and nicotine users
- ✓ Create an account to access the *General Snus* website

**Ensures all website visitors are verified adults 21+ who are also current tobacco and nicotine consumers**



# Responsible Marketing of Our Products

## Age-Gated Website

### Consumers must successfully:

- ✓ Verify their age
- ✓ Confirm they are current tobacco and nicotine users
- ✓ Create an account to access the *General Snus* website

**Ensures all website visitors are verified adults 21+ who are also current tobacco and nicotine consumers**

**The Authorized Modified Risk Claim is Currently Used  
Only on the Age-Gated *General Snus* Website**

# Visit GeneralSnus.com

## THE ORIGINAL SWEDISH SNUS

Register now to start enjoying everything General Snus has to offer:

- ✓ Discover new savings every month
- ✓ Get exclusive offers
- ✓ Learn more about snus
- ✓ Stay up to date on the latest

REGISTER NOW

ALREADY REGISTERED? SIGN IN.

E-MAIL ADDRESS

PASSWORD

SIGN IN

[Forgot password?](#)

**WARNING:** This product can cause mouth cancer.



# Confirm They Are a Current Tobacco/Nicotine User

REGISTRATION

Cancel X

123

Birthdate


TOBACCO USER?

Are you a current tobacco/nicotine user?

YESNO

Virginia

23060



WARNING: This product is not a safe alternative to cigarettes.

# If They Are Not a Current TNP User, Access is Denied

## **ACCESS DENIED**

General Snus products are only for current tobacco or nicotine users, age 21+. Since you're not a current tobacco or nicotine user, there's no need to register on our website because General isn't for you.

# Registration Process – Age Verification

**REGISTRATION**Cancel X

1

2

3

**Birthday**

<div>MONTH</div>	<div>DAY</div>	<div>YEAR</div>
------------------	----------------	-----------------

General Snus is for adult tobacco and nicotine consumers 21+ only. To make sure only people that should be enjoying snus are using our site, please complete an age verification process before continuing. This helps ensure our products are used responsibly.

**Personal information**

<div>LEGAL FIRST NAME</div>	PREFERRED FIRST NAME	<div>LAST NAME</div>
<div>STREET ADDRESS</div>		<div>CITY</div>
<div>STATE</div>		<div>ZIP CODE</div>

WARNING: Smokeless tobacco is addictive.



# Registration Process – Create an Account

[← Back](#)

REGISTRATION

[Cancel X](#)

✓

✓

3

Account information

EMAIL	CONFIRM EMAIL
PASSWORD	CONFIRM PASSWORD

PHONE NUMBER (OPTIONAL)

HOW DID YOU HEAR ABOUT US

ENTER YOUR INITIALS

By entering my initials, I understand that the content of this site is tobacco-related and I'm verifying that I'm at least 21 years of age or older as may be required by state or local law.

REGISTER

By entering my initials, I understand that the content of this site is tobacco-related and I'm verifying that I'm at least 21 years of age or older as may be required by state or local law. I understand my contact information and

**WARNING:** This product can cause mouth cancer.



# Select “Modified Risk” from the Navigation Bar



# View Claim on “Modified Risk” Website Page

*Using General Snus instead of cigarettes puts you at a lower risk of mouth cancer, heart disease, lung cancer, stroke, emphysema, and chronic bronchitis*

Even though we've already made history, our eyes remain firmly fixed on the future – a future free from cigarette smoke, where the choice is always clear.

## ABOUT GENERAL & SNUS











**WARNING:** Smokeless tobacco is addictive.











# Steps Required to View the MRTP Claim

<b>Visit GeneralSnus.com</b>	
<b>Select “Register Now”</b>	
<b>Identify as a current tobacco/nicotine user</b>	
<b>Provide personal information for age verification</b>	
<b>Be successfully age-verified by a third party</b>	
<b>Provide communication preferences</b>	
<b>Create an account username and password</b>	
<b>Click on “MODIFIED RISK”</b>	

# Expanded Use of the MRTP Claim











<b>General Snus Products</b> (Authorized in 2019)	
<b>Brand website</b>	
<b>Email and direct mail to 21+ age-verified consumers</b>	
<b>Point-of-sale</b>	
<b>Print advertising in publications where 85% or more of the population is 21+</b>	
<b>Other age-verified platforms (e.g., social media and digital platforms)</b>	

# Expanded Use of the MRTP Claim

	<b>General Snus Products</b> (Authorized in 2019) *
<b>Brand website</b>	
<b>Email and direct mail to 21+ age-verified consumers</b>	
<b>Point-of-sale</b>	
<b>Print advertising in publications where 85% or more of the population is 21+</b>	
<b>Other age-verified platforms (e.g., social media and digital platforms)</b>	

\* Check marks designate current marketing strategies using the modified risk claim.  
**Dashes** indicates areas for potential expanded use of the claim through additional marketing

# Expanded Use of the MRTP Claim

	<b>General Snus Products</b> (Authorized in 2019)*	<b>Copenhagen Classic Snuff</b> (Authorized in 2023)*
Brand website		
Email and direct mail to 21+ age-verified consumers		
Point-of-sale		
Print advertising in publications where 85% or more of the population is 21+		
Other age-verified platforms (e.g., social media and digital platforms)		

\* Check marks designate current marketing strategies using the modified risk claim.  
**Dashes** indicates areas for potential expanded use of the claim through additional marketing

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# Conclusions

**Gerry Roerty**

Vice President, Legal and General Counsel

# The Collective Evidence Supports Renewal of the *General Snus* MRTPA

**Since 2015, required PMSS requirements have been fulfilled with no FDA action**

- **There are no new questions of public health**
- **The reduced risk information remains accurate**
  - Desired impact regarding individual tobacco users
  - Desired population level impact

# The Collective Evidence Supports Renewal of the *General Snus* MRTPA

**Since 2015, required PMSS requirements have been fulfilled with no FDA action**

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  - Desired impact regarding individual tobacco users
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**Preponderance of real-world scientific evidence and data continues to demonstrate the harm reduction potential of *General Snus* with the reduced risk claim**

***General Snus* modified risk granted orders should be renewed**

# ***General Snus***

## **MRTP Renewal Tobacco Products Scientific Advisory Committee Meeting**

Swedish Match USA, Inc.

June 26, 2024



***Backup Slides Shown***

# Studies Suggest Users Will Transition from Smoking to Using *General Snus*, Not Vice Versa



“According to the applicant, there is little evidence that snus use leads to future cigarette smoking and that longitudinal and cross-sectional studies conducted on snus use in Sweden and other Scandinavian countries suggest that snus use is associated with a reduced risk of becoming (or continuing to be) a regular smoker. These longitudinal studies suggest that **users will transition from cigarettes to snus, rather than switching from snus to cigarettes.**”

*-FDA 2015 PMTA TPL  
(emphasis added)*

# Rotating Smokeless Warnings

- **Since July 22, 2010, smokeless tobacco product packaging and advertising must bear one of the following required warning label statements:**
  - **WARNING:** This product can cause mouth cancer.
  - **WARNING:** This product can cause gum disease and tooth loss.
  - **WARNING:** This product is not a safe alternative to cigarettes.
  - **WARNING:** Smokeless tobacco is addictive.