

3.2.: DESCRIPTION OF CONDITIONS FOR USE AND ACTUAL USE

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3.2. INTRODUCTION

Sections 911 (d)(2) and (d)(6) of the Food Drug and Cosmetics (FD&C) Act requires a Modified Risk Tobacco Product Application (MRTPA) to include:

- “(2) the conditions for using the product;” and
- “(6) data and information on how consumers actually use the tobacco product.”

We address these requirements in two sections for the candidate product, which is a grandfathered product (FDA Grandfather Status # GF1200194) ([Appendix 2.3-1](#)), commercially marketed in the U.S. as of February 15, 2007. As such, it is not a new tobacco product, as defined by FDCA Section 910(a)(1) and does not require premarket review and authorization¹:

1. **Section 3.2.1 - Conditions for using the product.** The candidate product is similar to the traditional moist smokeless tobacco (MST) products sold in the market and has been available in the U.S. for almost two centuries. The conditions for using the candidate product, therefore, are well established from its long history of use.

As the candidate product does not require specific instructions for use, our assessment of the “conditions for using the product” describes how consumers use the product, including the length of time of a typical use occasion.

2. **Section 3.2.2 - How consumers actually use the product.** We define “actual use of the product” to include frequency and quantity of use and use with other tobacco products. Because the design features of the candidate product are similar to other MST products currently sold in the U.S. (Section 2.3), we draw upon existing data on actual MST use behavior under real-world conditions. We present data for MST consumers overall and, where available, for MST consumers who report Copenhagen® Snuff Fine Cut as their usual brand,² as this includes use behaviors for both the brand and form (fine cut MST) of the candidate product.³ In addition to showing data for MST consumers overall (*Total MST*), we present data for exclusive MST consumers⁴ (*Exclusive MST*) and dual users, i.e., those MST consumers who also currently smoke cigarettes (*MST & Cigarettes*). These user groups represent the range of use patterns that can be anticipated in the context of marketing the candidate product with the proposed modified risk claim, including the behavior patterns among those who switch completely from cigarettes to the candidate product. Thus, we infer “actual use” of the candidate product with the proposed modified risk claim from this information.

¹ Copenhagen® Fine Cut and variants thereof have been on the market since 1822. Since 2007, USSTC made minor modifications to Copenhagen® Snuff Fine Cut, which are the subject of a separate pending Substantial Equivalence review. The candidate product subject to the MRTPA is the product for which FDA granted grandfathered status (Grandfather Number – GF1200194) on November 1, 2012.

² The Population Assessment of Tobacco and Health (PATH) Study includes data at the brand style level, including the brand style: Copenhagen® Snuff. The form of Copenhagen® Snuff is Fine Cut.

³ Although the Copenhagen® Snuff Fine Cut currently sold in the marketplace is the provisional version of the grandfathered candidate product, we do not expect the minor modifications to alter the actual use behavior.

⁴ “Exclusive MST” is in relation to cigarette smoking. These consumers may currently use other types of tobacco products, but not cigarettes.

Ultimately, a number of factors will determine the actual use of the candidate product, including marketing and advertising with the proposed modified risk claim and adult tobacco consumer (ATC) preferences, which are best represented in a real-world setting of the marketplace. Thus, we will further characterize actual use behavior with the candidate product through postmarket surveillance under actual, marketplace conditions, following FDA authorization to market the candidate product with the proposed modified risk claim.

We use diverse sources to address conditions for and actual use of the product:

1. We present analyses among respondents age 18 or older from two major national surveys: National Survey on Drug Use and Health (NSDUH) and Population Assessment of Tobacco and Health (PATH). Each survey provides nationally representative data on tobacco product use behavior and a view of the broader population of adult smokeless tobacco consumers.⁵
 - a. Specifically, we analyzed 2014⁶ NSDUH data that includes measures of “snuff” use where snuff is defined as “...sometimes called dip. Snuff is a finely ground form of tobacco that usually comes in a container called a tin. You can use snuff by placing a pinch or dip in your mouth between your lip and gum or between your cheek and gum...” (2014 NSDUH Questionnaire). The definition of snuff includes MST products. For consistency, we refer to “snuff” as MST in these sections. (See [Appendix 3.2-2](#) for detailed description of our analyses of NSDUH data.)
 - b. With respect to PATH, we analyzed Wave 1 data collected in 2013 and 2014. The definition of smokeless tobacco (ST) in PATH is broader to include “loose snus, moist snuff, dip, spit or chewing tobacco” (PATH Wave 1: Questionnaire for adults). The PATH data also includes a separate classification for “snus pouches” (Cheng et al., 2017). We focused our analyses on the PATH ST classification that excludes snus pouches and used the term “MST” to refer to ST in these sections. PATH also includes data specific to individual brand styles. Thus, we report data for MST consumers overall and for MST consumers who report their usual brand as Copenhagen® Snuff. ([Appendix 3.2-1](#) for detailed description of our analyses of PATH data.)
2. Additionally, we include findings from studies published in the scientific literature. Publications reporting how consumers use ST span a wide range of designs, methodologies, and measures. The type of ST is often not specified in these studies. While not all studies include nationally representative samples, they contribute to the overall understanding of how consumers use MST. Section [7.5.8-1](#) and [7.5.8-2](#) provides a complete review of the literature.

⁵ A wide range of smokeless tobacco (ST) products exist in the marketplace. We define the type of ST included in the data drawn from each information source presented in this section. Where possible, we sought to include data most relevant to the candidate product. Each definition included in these studies and data presented in these sections would include consumers of Copenhagen® Snuff Fine Cut.

⁶ The definition of ST products in NSDUH was expanded in 2015 to combine snuff and chewing tobacco, and add snus. We focused our assessment on forms of ST most similar to the candidate product, loose snuff; therefore, we limited our analyses to 2014 data.

3. Finally, we draw upon our own studies of ATC, which include observations specific to the candidate product:
- Adult Tobacco Consumer Tracking Study (Tracking Study).** Altria Client Services LLC (ALCS) conducts an on-going, nationally representative, mixed-mode tracking survey to measure tobacco product use prevalence by category and segment among adult respondents. The survey was launched in July 2013. The Tracking Study recruits approximately 2,400 legal-age adults per month through a mix of cell phone and landline calls, which is regularly rebalanced to align with findings from the NHIS Wireless Substitution reports (Blumberg & Luke, 2017). We present analyses of data for the prior 24 months ending in August 2017. We assess the form of ST (e.g., loose-fine cut, loose-long cut, pouch) and brand that consumers use regularly in our Tracking Study. We report information for consumers of MST⁷ overall and for consumers who report “fine cut” as their regular form of MST. We also report data for consumers who report (1) “fine cut” as their regular form and (2) “Copenhagen®” as their regular brand. For simplicity, we refer to this group as Copenhagen® Fine Cut. (See Appendix 3.2-4 for detailed descriptions of our analyses of Tracking Study data.)
 - Adult MST Consumer Behavior Study (Consumer Behavior Study).** ALCS assessed how ATC use MST, snus and/or cigarettes in the Consumer Behavior Study. We conducted this online survey in August 2013 among 1,033 ATC age 21 to 64 years old. This study defined ATC as those who used MST, snus, and/or smoked cigarettes in the past 30 days and indicated that they are “currently using” that tobacco product. The sample was designed to be representative of MST, snus, and cigarette consumers and weighted by gender, age, region, education, and regular brand share. While we assessed use behaviors at the category level, the sample included consumers of diverse brands and varieties, including Copenhagen® Snuff Fine Cut. We present results for participants who reported using MST⁸ irrespective of their use of other tobacco products (n=485), MST exclusive of cigarettes (n=271), and MST and cigarettes (n=214).⁹ (See Appendix 3.2-3 for detailed descriptions of our analyses of Consumer Behavior Study data.)
 - Clinical Study.** We also include data specific to the candidate product from a clinical study (Study #ALCS-RA-17-02; Appendix 7.3.1-1) in which the study participants used the candidate product¹⁰ under *ad libitum* use conditions in the clinic for a period

⁷ The definition of MST in our analyses of Tracking Study data included “loose MST/dip,” excluding MST sold in pouches. “Loose MST/dip” include fine cut and long cut products.

⁸ The definition of MST in the Consumer Behavior Study included MST sold in pouches.

⁹ Due to survey routing patterns to minimize overall survey length, participants may not have been asked usage questions for every tobacco product they use. Specifically, 3 of the 271 exclusive MST users and 44 of the 214 dual users of MST and cigarettes were not asked questions about their MST use behavior. Thus, the total number of adult MST consumers analyzed on MST use behaviors was 438 (268 exclusive MST users (271 minus 3) plus 170 dual users (214 minus 44) who were asked the MST use behavior questions), rather than 485 (271 exclusive MST users plus 214 dual users). Similarly, 38 of the 214 dual users were not asked questions about their cigarette use behavior. Thus, the total number of dual users analyzed on cigarette use behaviors was 176 (214 dual users minus 38 who were not asked about their cigarette use).

¹⁰ The candidate product used in the clinical study was the grandfathered version manufactured using identical specifications as Copenhagen® Original Fine Cut Snuff, which was marketed on or before February 2007.

of four hours ([Appendix 7.3.1-1](#)). We conducted this study in 2017 to characterize nicotine pharmacokinetics, use behavior, and subjective effects of the candidate product in comparison to study participants' own brand of cigarettes and nicotine polacrilex gum. The study sample comprised 24 adult smokers who use MST (19 men and five women). Study staff recorded subjects' actual use behavior of the candidate product during the four-hour *ad libitum* period.

We present an overview of the measures reported in this section that were obtained from these studies, including NSDUH and PATH, in Table 3.2-1. While these studies differed in several respects (e.g., definitions of MST, sampling methods, study populations, mode of survey administration, definitions of measures, and wording of questions), collectively and complemented by published literature, they provide a comprehensive view of conditions for use and actual use behavior.

Table 3.2-1: Conditions for Use and Actual Use Behavioral Measures by Study

Measure	Population Assessment of Tobacco and Health (PATH, 2013-2014)	National Survey on Drug Use and Health (NSDUH, 2014)	ALCS Tracking Study (2015-2017)	ALCS Consumer Behavior Study (2013)	ALCS Clinical Study (2017)
Section 3.2.1: The Conditions for Using the Tobacco Product					
Length of time a dip is kept in mouth				✓	✓ ¹
Section 3.2.2: How Adult Consumers Actually Use the Product					
Number of days using MST (in past 30)	✓	✓	✓	✓	
Portion size					✓ ¹
Number of dips or use occasions per day	✓			✓	✓ ¹
Number of cans of MST used per day			✓		
Section 3.2.3: Concurrent Use of Multiple Products Containing Nicotine or Tobacco					
Dual use ² of MST and cigarettes	✓	✓	✓		
Number of days smoking in past 30 days (among dual)	✓	✓	✓	✓	
Cigarettes smoked per day (among dual)	✓	✓	✓	✓	

¹ Measure was limited to four-hour *ad libitum* period

² Dual use is defined as reported past 30-day use of MST and past 30-day use of cigarettes. While a sizeable proportion of MST users consume other tobacco products, we focus our discussion on dual use of MST with cigarettes because this is the largest proportion among dual users.

Limitations of the data sources:

1. Potential response and sampling biases are inherent limitations of survey research. For example, each survey study uses self-report methods to assess past behaviors, which are subject to recall bias. Although survey research literature documents recall bias, this phenomenon is a well-accepted limitation in survey research. To help minimize this limitation, many of the measures we relied on are based on past 30-day tobacco use.
2. The Consumer Behavior Study relied on online panels, which may limit the generalizability of findings.
3. The controlled environment and limited sample size of the clinical study can limit the generalizability of those results.

While we recognize these limitations, we draw on these diverse studies with complementing features to provide a more comprehensive view of MST use and to infer actual use behavior of the candidate product.

3.2.1. The Conditions for Using the Tobacco Product

In the Draft MRTPA Guidance, FDA provides recommendations regarding types of information applicants could provide to meet the statutory requirement to include the conditions for using the product. In Section V(A)(2) of the Draft Guidance, FDA recommends inclusion of:

- a full narrative description of the way in which a consumer will use the tobacco product, including a description of how a consumer operates the product;
- a quantitative description of the length of time it takes a consumer to consume a single unit of the product, including information about the pattern of use during that time (i.e., intermittent or continuous);
- specific instructions on how to use and store the product to get the proposed reduction in risk or exposure; and
- specific instructions on how to avoid using the product in a way that could reduce or eliminate the potential benefit or increase the risk of using the product.

3.2.1.1. Description of Use

ATC use the candidate product in the same manner as other MST products, by placing a pinch (also known as quid or dip) into the mouth between the cheek or lip and gum. The ATC typically holds the product in the mouth, expectorates “juice” (a mix of saliva, tobacco particles, and extracted materials such as flavors), and removes the product from the mouth at the end of use. Adult MST consumers appear to vary with respect to spitting and/or swallowing tobacco “juice.” Studies that assessed whether ATC “Never,” “Sometimes,” or “Always” swallow tobacco “juice” indicated that consumers report each behavior in generally equal proportions (Boyle, Jensen, Hatsukami, & Severson, 1995; Ebbert et al.,

2004; Thomas et al., 2006). While some ATC may swallow the “juice,” which includes some tobacco particles, the vast majority of the tobacco is discarded after use.

3.2.1.2. Length of Time to Consume a Single Unit

The duration of a single dip varies. In our Consumer Behavior Study ([Appendix 3.2-3](#)), about half of adult MST consumers (55%) report a dip duration between 15 and 45 minutes, 25% report a dip duration of more than 45 minutes, and 20% report using the dip for up to 15 minutes (Table 3.2-2). Exclusive MST consumers are more likely to report a longer dip duration than dual users of MST and cigarettes: 31% of exclusive users report a dip duration of more than 45 minutes, compared to 14% of dual users. Conversely, 31% of dual users report a dip duration of up to 15 minutes, compared to less than 15% of exclusive MST consumers.

Table 3.2-2: Average Number of Minutes a Dip Is Kept in Mouth (Dip Duration)

Length of Time	Total Adult MST Consumers (n=438)	Exclusive Adult MST Consumers (n=268)	Adult MST & Cigarette Consumers (n=170)
< 5 minutes	2%	<1%	5%
5-15 minutes	18%	14%	26%
15-30 minutes	38%	34%	45%
30-45 minutes	17%	21%	11%
> 45 minutes	25%	31%	14%

Source: Analyses of ALCS Consumer Behavior Study data: [Appendix 3.2-3, Table 1](#)

MST = Moist Smokeless Tobacco

Notes: Percentages may not add to 100 due to rounding.

Clinical study observations on dip duration are consistent with our Consumer Behavior Study results. Participants in the clinical study used the candidate product for an average of 37.2 minutes (SD = 24.2) during the *ad libitum* period, with a large variability (Coefficient of Variation ~65%).¹¹ Studies that aimed specifically to characterize ST topography indicated similar results. [Hatsukami, Keenan, & Anton \(1988\)](#) conducted a study of topographical features of ST use. From a sample of 56 adult male college students, the investigators report the mean dip duration was 39.9 minutes (SD = 16.5). Consistent with these findings, from a survey of 30 male ST consumers, [Hatsukami et al. \(1991\)](#) report an average dip duration of 39.6 minutes (SD = 18.3). In a larger scale survey of adult ST consumers seeking tobacco cessation treatment (n=402), [Hatsukami et al. \(1999\)](#) report an average dip duration of 46.5 minutes (SD = 34.9). Large variability was consistently evident in the literature reports as well as our clinical study, indicating that individual product use behavior is highly variable. Despite this variability, our research and supporting evidence suggest an average generally in the range of 15 to 45 minutes for most adult MST consumers.

¹¹ Source: [Appendix 7.3.1-1, Clinical Study Report, Table 7](#)

3.2.1.3. Specific Instructions on How to Use and Store the Product to Get the Proposed Reduction in Risk or Exposure

Once authorized, the proposed modified risk claim communicates to smokers that switching completely to the candidate product reduces the risk of lung cancer. Beyond this message, there are no specific use instructions for the candidate product. MST has a long history in the U.S. marketplace, and ATC know how to use the candidate product. In addition, no product storage instructions (e.g., refrigeration) are necessary for the candidate product.

3.2.1.4. Specific Instructions on How to Avoid Using the Product in a Way That Could Reduce or Eliminate the Potential Benefit or Increase the Risk of Using the Product

Once authorized, the proposed modified risk claim communicates to smokers that switching completely to the candidate product reduces the risk of lung cancer. USSTC provides no other specific instructions to avoid using the candidate product in a way that could reduce or eliminate the potential benefit or increase the risk of use. ATC know how to use the candidate product and that use provides the potential benefit for ATC who switch completely from cigarettes. Thus, no further use instructions are needed to get the proposed reduction in risk.

3.2.2. How Consumers Actually Use the Product

In the Draft MRTPA Guidance (2012), FDA provides recommendations regarding types of information applicants could provide to meet the statutory requirement to include data and information on how consumers actually use the tobacco product. In Section V(A)(6) of the Draft Guidance (2012), FDA recommends that the application address:

- whether consumers can and are likely to comply with any instructions for product use;
- the number of units of the product consumed per day and the way in which individuals consume each unit of the product; and
- concurrent use of multiple products containing nicotine or tobacco.

Further, in Section VI(B)(3), the Draft MRTPA Guidance states “actual use studies should allow consumers to interact freely with the product in real-world conditions.” It is difficult to replicate real-world conditions to assess actual use of the candidate product with its proposed modified risk claim, as it currently does not exist in the marketplace. Much of the information we present in this section, however, is aligned with the Draft Guidance and based on survey research among consumers as they behave in the real world. Postmarket surveillance will provide the best assessment of whether marketing the candidate product with the proposed modified risk claim will result in any differences in adult consumer use behavior under real-world settings.

3.2.2.1. Whether Consumers Can and Are Likely to Comply with Any Instructions for Product Use

The candidate product does not require specific instructions for use, and USSTC MST products currently sold in the market do not contain any instructions for use. MST has a long history in the U.S. marketplace, and ATC know how to use the candidate product. Thus, instructions for using the product are not needed.

3.2.2.2. The Number of Units of the Product Consumed Per Day and the Way in Which Individuals Consume Each Unit of the Product

We will obtain this information through postmarket surveillance under real-world conditions following FDA authorization of the proposed modified risk claim. Given that the candidate product is similar to other current MST products, we provide frequency and quantity of use data for these products as used in the marketplace.

Number of days of MST use during the past 30 days. Adult MST consumers¹² report using MST between 21 to 23 days in the past 30 days (Table 3.2-3). Copenhagen® Snuff / Copenhagen® Fine Cut adult consumers report using MST on a more frequent basis, ranging from 26 to 28 days in the past 30 days. Exclusive MST adult consumers tend to report use on more days than those who report dual use with cigarettes.

Table 3.2-3: Average Number of Days MST Used During the Past 30 Days

MST and Cigarette Use Status	Copenhagen® Snuff ¹	Copenhagen® Fine Cut	Fine Cut User (form level)	Total MST Users (category level)			
	PATH Wave 1 (2013-2014)	ALCS Tracking Study (2015-2017)	ALCS Tracking Study (2015-2017)	PATH Wave 1 (2013-2014)	NSDUH (2014)	ALCS Tracking Study (2015-2017)	ALCS Consumer Behavior Study (2013)
Total MST	28.0 (n=104)	26.3 (n=128)	25.0 (n=307)	22.7 (n=1,625)	20.7 (n=1,581)	23.2 (n=1,416)	22.0 (n=438)
Exclusive MST ²	28.7 (n=84)	27.6 (n=104)	27.3 (n=244)	25.8 (n=941)	23.4 (n=891)	25.8 (n=1,018)	25.2 (n=268)
MST & Cigarettes	24.9 (n=20)	20.8 (n=24)	16.2 (n=64)	17.8 (n=682)	16.1 (n=690)	16.6 (n=398)	16.8 (n=170)

Sources: ALCS Analyses of PATH data: [Appendix 3.2-1, Table 1a, Table 1b, Table 2a, Table 2b](#); ALCS Analyses of NSDUH data: [Appendix 3.2-2, Table 1, Table 2](#); Analyses of ALCS Tracking Study data: [Appendix 3.2-4, Table 1](#); Analyses of ALCS Consumer Behavior Study data: [Appendix 3.2-3, Table 2, Table 3](#)

PATH = Population Assessment of Tobacco and Health; NSDUH = National Survey on Drug Use and Health; MST = moist smokeless tobacco

¹Among past 30-day users who had ever used ST fairly regularly and indicated Copenhagen® Snuff was their usual brand.

²Exclusive of cigarette smoking

¹² Unless otherwise noted, our analyses of data from PATH, NSDUH, our Tracking Study and Consumer Behavior Study define current adult tobacco consumers as those reporting use of the specified tobacco product in the past 30 days.

Number of units of product consumed per day and portion size. Consumption has been measured in various ways, including use occasions per day, cans per day, and cans per week. Adult MST consumers report using MST on average six times a day on days used (Table 3.2-4). Adult consumers of Copenhagen® Snuff report using MST on average nine times a day. The number of use occasions tends to be higher among exclusive users, compared to dual users.

Table 3.2-4: Number of MST Use Occasions on Days Used

Number of Daily Use Occasions	Copenhagen® Snuff ¹ User			Total MST Users (category level)					
	PATH Wave 1 (2013-2014)			PATH Wave 1 (2013-2014)			ALCS Consumer Behavior Study ² (2013)		
	Total MST (n=104)	Exclusive MST ³ (n=84)	MST & Cigarettes (n=20)	Total MST (n=1,611)	Exclusive MST ³ (n=936)	MST & Cigarettes (n=673)	Total MST (n=438)	Exclusive MST ³ (n=268)	MST & Cigarettes (n=170)
Up to 5	33%	29%	55%	60%	52%	73%	62%	58%	67%
6-10	46%	53%	16%	29%	36%	18%	26%	28%	22%
More than 10	20%	18%	29%	11%	12%	9%	13%	13%	11%
<i>Average Number of Occasions</i>	<i>8.9</i>	<i>9.1</i>	<i>8.0</i>	<i>6.0</i>	<i>6.6</i>	<i>5.2</i>	<i>6.1</i>	<i>6.4</i>	<i>5.6</i>

Sources: ALCS Analyses of PATH data: [Appendix 3.2-1](#), [Table 6a](#) through [Table 10b](#); Analyses of ALCS Consumer Behavior Study data: [Appendix 3.2-3](#), [Table 4](#), [Table 5](#), [Table 6](#)

PATH = Population Assessment of Tobacco and Health; MST = moist smokeless tobacco

Notes: Percentage may not add to 100 due to rounding.

¹ Among past 30-day users who had ever used ST fairly regularly before the assessment and indicated Copenhagen® Snuff was their usual brand.

² Data shown was in response to question specific to days during the week. Average number of use occasion on weekends was 6.3 among Total MST, 6.6 among Exclusive MST, and 5.8 among MST & Cigarette consumers (See analyses of ALCS Consumer Behavior Study data: [Appendix 3.2-3](#), [Table 7](#), [Table 8](#)

³ Exclusive of cigarettes.

Participants in our clinical study used the candidate product an average of 2.3 times (SD = 1.27) during the four-hour *ad libitum* period.¹³ Extrapolating to a longer time period, this frequency is within the range of daily use occasions measured in survey research. Presuming 16 waking hours, use during the *ad libitum* period equates to approximately nine use occasions in the day.

Adult MST consumers generally consume about a half can of MST on days they use MST. Based on our Tracking Study, adult MST consumers report using slightly more than a half can (0.56) per day on days used ([Table 3.2-5](#)). The can per day consumption is comparable among fine cut consumers (0.59) and Copenhagen® Fine Cut consumers (0.57). Similar to the

¹³ Source: [Appendix 7.3.1-1, Clinical Study Report, Table 7](#)

observed patterns for use occasions, can consumption is generally higher among exclusive MST users than among dual users.

Data from our clinical study show results consistent with these use patterns. For example, the average portion size of the candidate product used by participants during the *ad libitum* period was 2.46 grams (SD \pm 2.36).¹⁴ Using this average portion size, the number of portions in a 34.02-gram can of Copenhagen® equates to roughly 14 portions per can. This estimate of 14 portions per can is generally in line with the observations from survey research: Six to nine use occasions (Table 3.2-4) translates to .43 to .64 cans per day, respectively. This range of cans per day is in accord with cans per day measured in survey research (Table 3.2-5).

Table 3.2-5: Number of Cans Consumed on Days Used

Number of Cans/Day	ALCS Tracking Study (2015-2017)		
	Total MST Users (n=1,416)	Fine Cut User (n=307)	Copenhagen® Fine Cut User (n=128)
< ¼ Can	25%	25%	26%
¼ Can	17%	14%	15%
½ Can	25%	24%	23%
¾ Can	8%	8%	8%
1 Can	19%	21%	21%
1 ½ Cans	3%	3%	4%
> 1 ½ Cans	4%	5%	3%
Don't Know	<1%	1%	1%
<i>Average Number of Cans</i>	<i>0.56</i>	<i>0.59</i>	<i>0.57</i>
<i>Average Number of Cans among Exclusive MST¹</i>	<i>0.60 (n=1,018)</i>	<i>0.61 (n=244)</i>	<i>0.56 (n=104)</i>
<i>Average Number of Cans among MST & Cigarettes</i>	<i>0.44 (n=398)</i>	<i>0.55 (n=64)</i>	<i>0.59 (n=24)</i>

Sources: Analyses of ALCS Tracking Study data: [Appendix 3.2-4, Table 2](#)

MST = moist smokeless tobacco

Notes: Percentage may not add to 100 due to rounding.

¹ Exclusive of cigarettes

We find generally consistent results on MST consumption in the published literature. Published literature values for MST consumption are typically stated as cans per week and not cans per day. For example, [Hatsukami and colleagues \(1999\)](#) report an average of 3.7 cans per week (SD = 2.5; range = 1-22) among adult MST consumers seeking treatment for tobacco cessation. These data are consistent with the observation that adult MST consumers use about a half can per day on average.

¹⁴ Source: [Appendix 7.3.1-1, Clinical Study Report, Table 7](#)

3.2.3. Concurrent Use of Multiple Products Containing Nicotine or Tobacco

We define concurrent use as reported past 30-day use (i.e., current use) of more than one tobacco product. Concurrent use may characterize current use of two products (“dual use”) or more than two products (“poly use”).

In this section, we report prevalence of concurrent use of MST and other tobacco products. In addition, we describe the number of days smoked in the past 30 days and the number of cigarettes smoked on days cigarettes were smoked by dual users of MST and cigarettes. We focus on dual use of MST and cigarettes because, among tobacco products, this type of dual use may result in the greatest health risks, and cigarette smoking represents the predominant form of tobacco use in the U.S. In addition, our proposed modified risk claim focuses on complete switching from cigarettes to the candidate product (an MST product). Detailed discussions of dual use patterns among MST users can be found in Section 7.5.2-1, Section 7.5.2-2, and Section 6.3.

The proportion of dual users of MST and cigarettes varied across the studies reviewed. Based on our analysis of 2014 NSDUH data, 1% of the entire U.S. adult population report past 30-day use of both MST and cigarettes.¹⁵ Among adult MST consumers, 37% report past 30-day use of cigarettes (Table 3.2-6).

Our analyses of PATH data show that 40% of total adult MST consumers report past 30-day use of cigarettes, whereas 20% of Copenhagen® Snuff consumers report past 30-day use of cigarettes (Table 3.2-6).

In our tracking study, 30% of total adult MST consumers report past 30-day use of cigarettes. Similar to PATH study results, 19% of Copenhagen® Fine Cut consumers report past 30-day cigarette smoking (Table 3.2-6).

Table 3.2-6: Percentage Reporting Past 30-Day Use of Other Tobacco Products Among Adult Past 30-Day MST Consumers

Tobacco Products	Copenhagen® Snuff ¹ User	Copenhagen® Fine Cut User	Fine Cut User (form level)	Total MST Users (category level)		
	PATH Wave 1 (2013-2014) (n=110)	ALCS Tracking Study (2015-2017) (n=128)	ALCS Tracking Study (2015-2017) (n=307)	PATH Wave 1 (2013-2014) (n=1,825)	NSDUH (2014) (n=1,581)	ALCS Tracking Study (2015-2017) (n=1,675)
Cigarettes	20%	19%	21%	40%	37%	30%

¹⁵ Source: ALCS Analyses of NSDUH data: [Appendix 3.2-2, Table 10](#)

Table 3.2-6: Percentage Reporting Past 30-Day Use of Other Tobacco Products Among Adult Past 30-Day MST Consumers (Continued)

Tobacco Products	Copenhagen® Snuff ¹ User	Copenhagen® Fine Cut User	Fine Cut User (form level)	Total MST Users (category level)		
	PATH Wave 1 (2013-2014) (n=110)	ALCS Tracking Study (2015-2017) (n=128)	ALCS Tracking Study (2015-2017) (n=307)	PATH Wave 1 (2013-2014) (n=1,825)	NSDUH (2014) (n=1,581)	ALCS Tracking Study (2015-2017) (n=1,675)
Cigars	14%	11%	11%	22%	15%	13%
Pipe Tobacco	1%	4%	2%	4%	2%	5%
E-Cigarettes	3%	8%	9%	16%	N/A ²	12%
Snus Pouches	3%	5%	6%	10%	N/A ²	9%
Chewing Tobacco	N/A ³	2%	1%	N/A ³	21%	2%
Dissolvable Tobacco Products (PATH)/Other Tobacco Derived Nicotine Product (Non-Vapor) (Tracking)	0%	0%	0.1%	1%	N/A ²	1%

Sources: ALCS analyses of PATH data: [Appendix 3.2-1, Table 11a, Table 11b](#); ALCS analyses of NSDUH data: [Appendix 3.2-2, Table 6](#); Analyses of ALCS Tracking Study data: [Appendix 3.2-4, Table 3](#)

PATH = Population Assessment of Tobacco and Health; NSDUH = National Survey on Drug Use and Health; MST = moist smokeless tobacco

¹ Among past 30-day users who had ever used ST fairly regularly before the assessment and indicated Copenhagen® Snuff was their usual brand.

² Product not included in survey

³ Product included in the ST definition

Frequency and amount of cigarette use among MST and cigarette dual users. Cigarette consumption among dual users is generally consistent across the surveys. Adult MST consumers, including fine cut and Copenhagen® Snuff/ Copenhagen® Fine Cut adult consumers, who report using cigarettes in the past 30 days report smoking an average of 23 to 26 days in the past 30 days¹⁶ ([Table 3.2-7](#)). The average number of cigarettes smoked on days smoked ranges from 11 to 16. The data suggest that Copenhagen® Snuff dual users smoke fewer cigarettes per day than overall MST dual users, but the data should be interpreted with caution due to the small sample size.

¹⁶ Excluding the 19 days observed in the NSDUH data.

Table 3.2-7: Past 30-Day Frequency and Amount of Cigarette Use on Days Used Among MST and Cigarette Dual Users

Cigarette Smoking Behavior	Copenhagen® Snuff ¹ User	Copenhagen® Fine Cut User	Fine Cut User (form level)	MST User (category level)			
	PATH Wave 1 (2013-2014) (n=20)	ALCS Tracking Study (2015-2017) (n=24)	ALCS Tracking Study (2015-2017) (n=64)	PATH Wave 1 (2013-2014) (n=713)	NSDUH (2014) (n=690)	ALCS Tracking Study (2015-2017) (n=495)	ALCS Consumer Behavior Study (2013) (n=176)
Average # of days smoked in past 30	24.6	26.4	26.0	24.6	19.2	25.1	22.9
Average # of cigarettes smoked per day	11.0	15.5	12.9	16.2 ²	NA ³	13.6	13.5 ⁴

Sources: ALCS analyses of PATH data: [Appendix 3.2-1, Table 12a, Table 12b, Table 14a, Table 14b](#); ALCS analyses of NSDUH data: [Appendix 3.2-2, Table 7](#); Analyses of ALCS Tracking Study data: [Appendix 3.2-4, Table 4, Table 5](#); Analyses of ALCS Consumer Behavior Study data: [Appendix 3.2-3, Table 9, Table 10](#)

PATH = Population Assessment of Tobacco and Health; NSDUH = National Survey on Drug Use and Health, MST = moist smokeless tobacco

¹ Among past 30-day dual users who had ever used ST fairly regularly before the assessment and indicated Copenhagen® Snuff was their usual brand

² n=710; ALCS analyses of PATH data: [Appendix 3.2-1, Table 14a](#)

³ NSDUH only provides categorical data; ALCS analyses of NSDUH data: [Appendix 3.2-2, Table 9](#)

⁴ Data shown was in response to question specific to days during the week. Average number of cigarettes smoked on days smoked on the weekend was 13.9 among dual users of MST and cigarettes; analyses of ALCS Consumer Behavior Study data: [Appendix 3.2-3, Table 11](#)

3.2.4. Summary

We focus our summary on data specific to Copenhagen® Snuff, where available, as this includes use behaviors for both the brand and form of the candidate product. Adult consumers of Copenhagen® Snuff report using MST on an average of 28 days within the month, over an average of nine use occasions on the days they use MST. The number of days and use occasions are slightly higher among Copenhagen® Snuff adult consumers compared to overall MST adult consumers.¹⁷

The average dip duration is generally in the range of 15 to 45 minutes for most adult MST consumers. Differences in frequency and quantity of use of MST tend to be associated with the use of cigarettes: dual users report using less MST than exclusive MST users. We observed this pattern for Copenhagen® Snuff adult consumers as well.

¹⁷ Usual brand is assessed in PATH only among ST users who report ever using ST fairly regularly. Some of the differences in use patterns between Copenhagen® Snuff adult consumers and other MST adult consumer groups (which are based only on past 30-day use) may be attributable to this additional criterion.

A smaller proportion of Copenhagen® Snuff adult consumers report dual use with cigarettes (20%) than total MST adult consumers (30-40% depending on the survey).

3.2.5. Conclusion

Based on similarity in form and brand, we infer use of the candidate product is likely most consistent with the use patterns of Copenhagen® Snuff adult consumers. These adult consumers tend to consume MST on more days and occasions per day and appear to be less likely to also report cigarette smoking than MST adult consumers overall.

The investigation of actual use of the product in-market with the proposed modified risk claim over time can be best ascertained under real-world conditions after FDA has granted market authorization for the proposed modified risk claim.

3.2.6. Literature Cited

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