

3.4 The Conditions for Using Camel Snus

TCA Section 911(d)(2) requires that applications for modified risk tobacco products include information regarding the “the conditions for using the product.” This section describes the conditions for using Camel Snus, including: (1) a description of the manner in which a consumer will use the product; (2) a description of the length of time it takes to consume a single unit of the product; (3) instructions on how to use (and store) the product to achieve the expected reduction in risk and (4) instructions on how to avoid using the product in a manner that could reduce or eliminate the expected benefit, or increase the risk associated with using the product (FDA MRTPA Draft Guidance 2012, p. 12). The information on conditions for use applies to each of the six Camel Snus styles in this Application, *i.e.*, Camel Snus Frost, Camel Snus Frost Large, Camel Snus Mellow, Camel Snus Mint, Camel Snus Robust and Camel Snus Winterchill.

3.4.1 The manner in which a consumer will use Camel Snus

Camel Snus is a pouched tobacco product that is intended to be placed in the mouth and used as is. It is not intended to be combusted. It is placed under the lip during use for a duration determined by the user. Typically, there is no expectoration (spitting) when using Camel Snus. The product is removed from the mouth after use and disposed of.

3.4.2 The length of time it takes to consume a single unit of Camel Snus

Camel Snus is used for a length of time determined by the user. Camel Snus flavor typically lasts approximately 30 minutes. Camel Snus is not consumed in its entirety. Rather, the Camel Snus pouch is removed from the user’s mouth after use.

3.4.3 Instructions on how to use Camel Snus to achieve the expected reduction in risk

The target audience for all proposed modified risk advertising is adult smokers (Section 4). RJRT has no interest in and does not want minors to purchase or possess any tobacco products, including Camel Snus. RJRT has no interest in and does not want to encourage non-users to use any tobacco products, including Camel Snus.

Smokers are instructed in the proposed advertising that the best way to reduce risk is to quit smoking and that a first step in that process can be to talk with their healthcare provider:

“If you’re a smoker concerned about the health risks from smoking, the best choice is to quit. A good place to begin is talking with a healthcare provider.”

Smokers who do not intend to quit using tobacco products are informed that they should consider switching from cigarettes to Camel Snus with emphasis on switching completely.

Advertising Execution 1: “Smokers who **switch completely** from cigarettes to Camel SNUS can significantly reduce their risk of lung cancer, oral cancer, respiratory disease, and heart disease.”

Advertising Execution 2: “Smokers who **SWITCH COMPLETELY** from cigarettes to Camel SNUS can greatly reduce their risk of lung cancer, oral cancer, respiratory disease, and heart disease.”

Advertising Execution 3: “Smokers who **SWITCH COMPLETELY** from cigarettes to Camel SNUS can greatly reduce their risk of lung cancer and respiratory disease.”

3.4.4 Instructions on how to avoid using Camel Snus in a manner that could reduce the expected benefit

In addition to emphasizing the message to smokers that they should switch completely to Camel Snus, the proposed advertising declares that no tobacco product is safe and that Camel Snus contains nicotine and is addictive ([Section 4](#)). Instructions on how to avoid using Camel Snus in a manner that could reduce the potential benefit include:

“Adults who do not use or have quit using tobacco products should not start.”

“Minors and pregnant women should never use tobacco products.”¹

“If you’re a smoker concerned about the health risks from smoking, the best choice is to quit. A good place to begin is talking with a healthcare provider.”

3.5 Data and Information on How Consumers Actually Use Camel Snus

[TCA Section 911\(d\)\(6\)](#) requires that applications for modified risk tobacco products include data and information “on how consumers actually use the tobacco product.” This section summarizes the available data and information on how consumers actually use Camel Snus, including: (1) whether consumers can and are likely to comply with any instructions for using Camel Snus necessary to achieve the expected reduction in risk, (2) the number of units (pouches) of Camel Snus consumed per day and (3) concurrent use of Camel Snus with multiple products containing nicotine or tobacco ([FDA MRTPA Draft Guidance 2012, pp. 14-15](#)). The data and information apply to each of the six Camel Snus styles in this Application, *i.e.*, Camel Snus Frost, Camel Snus Frost Large, Camel Snus Mellow, Camel Snus Mint, Camel Snus Robust and Camel Snus Winterchill.

3.5.1 Consumers can and are likely to comply with instructions for using Camel Snus necessary to achieve the expected reduction in risk

RJRT’s proposed modified risk advertisements communicate the key message that smokers who switch completely from smoking cigarettes to using Camel Snus can reduce their risk of developing serious chronic disease. The proposed advertisements also communicate several

¹ For Execution 1 of the proposed modified risk advertising for Camel Snus, the instructions that minors and pregnant women should never use tobacco products is presented in a plain text font. For Execution 2 and Execution 3 of the proposed advertising, font changes (bold and underline) were made to further emphasize this health risk information.

other important messages, including that persons who do not use tobacco should not use Camel Snus ([Section 4](#)).

In accordance with [TCA Section 911\(h\)\(1\)](#) and [FDA MRTPA Draft Guidance 2012](#), three separate comprehension and perceptions studies were conducted (one study for each proposed advertising execution) to assess the effects of the proposed advertisements for Camel Snus on current tobacco users' and non-users' (both former users and never users) understanding and application of the modified risk information provided ([Section 6.2](#)). The proposed modified risk advertisements convey the key message that Camel Snus is best used as a complete substitute for smoking and not as a supplement to smoking. Other messages that can help consumers understand the appropriate use of Camel Snus include that individuals who do not already use tobacco should not start using Camel Snus, Camel Snus should not be used by minors or pregnant women, and Camel Snus contains nicotine and is addictive.

To achieve the maximum individual and population-level reduction in risk, Camel Snus should be used by cigarette smokers and those smokers should switch completely from smoking cigarettes to using Camel Snus. In accordance with [TCA Section 911\(h\)\(1\)](#) and [FDA MRTPA Draft Guidance 2012](#), three separate likelihood of use studies were conducted (one study for each proposed advertising execution) to assess the effects of the proposed advertisements for Camel Snus on current tobacco users' and non-users' (both former users and never users) likelihood to use the product when modified risk information is provided ([Section 6.3](#)).

3.5.1.1 Consumers understand and thus can comply with instructions for using Camel Snus necessary to achieve the expected reduction in risk

RJRT's proposed modified risk advertisements stress that smokers must switch completely to using Camel Snus to reduce their risk of disease. Respondents in the comprehension and perceptions studies were shown the proposed modified risk advertisements and then asked to indicate what cigarette smokers should do in order to benefit from using Camel Snus. Across all three studies and in response to the three advertising executions, roughly three-quarters of respondents correctly understood that smokers should stop smoking completely and use Camel Snus instead. Very few respondents (3 – 4%) believed that using Camel Snus while continuing to smoke would deliver health benefits ([Section 6.2](#)).

From an individual health perspective, cigarette smokers who switch completely to using Camel Snus are likely to reduce their risk of smoking-related diseases. However, the greatest benefit and reduction in risk comes from quitting tobacco use altogether. The proposed modified risk advertisements explicitly communicate that quitting is preferred to switching to Camel Snus. Across all three of the comprehension and perceptions studies, strong majorities understood that quitting tobacco use altogether is the best choice for smokers ([Section 6.2](#)). Importantly, this was true among current tobacco users (89 – 91%), including those who were planning to quit (91 – 93%).

A concern regarding any modified risk advertising is that such advertising may unintentionally encourage use of the product among individuals who are not currently using tobacco. This

could add risk to the overall population rather than reduce it, and thus reduce the overall population health benefit. Findings from the comprehension and perceptions studies show that, following exposure to the proposed modified risk advertisements, very few respondents (5 – 6%) in the overall sample believed that non-users of tobacco should use Camel Snus ([Section 6.2](#)). This message was also well understood among non-users, including both former and never tobacco users, with only 3 – 6% giving an incorrect response. Thus, the proposed advertisements, which include the explicit statement that non-users of tobacco should not use Camel Snus, did not lead respondents to believe that Camel Snus should be used by those who do not currently use tobacco.

Included within the proposed modified risk advertisements is the statement that Camel Snus contains nicotine and is addictive. Respondents in the comprehension and perceptions studies understood that Camel Snus contains nicotine and is addictive, as 82% correctly endorsed this statement across the three executions ([Section 6.2](#)). Only 5 – 7% disagreed with the statement, whereas the remainder was not sure. Recognition that Camel Snus contains nicotine and is addictive was evident among both current tobacco users and non-users of tobacco.

The comprehension and perceptions studies also tested for potential generalization of the proposed modified risk advertising to other products in the same tobacco category (smokeless tobacco products other than Camel Snus) that do not currently have authorized modified risk advertising. In quantitative ratings, respondents consistently rated the risk of other smokeless tobacco products as modestly higher than Camel Snus, suggesting that respondents would not globally generalize the claims for Camel Snus to all smokeless products ([Section 6.2](#)).

Findings from the comprehension and perceptions studies, and the consistency of those findings across the three advertising executions, collectively show that consumers understand and can thus comply with instructions for using Camel Snus necessary to achieve the expected reduction in risk.

3.5.1.2 Consumers are likely to comply with instructions for using Camel Snus necessary to achieve the expected reduction in risk

Likelihood of use studies were conducted to assess consumers' responses for each of the three proposed Camel Snus modified risk advertisements ([Section 6.3](#)). The aim of the likelihood of use studies was to estimate the relative appeal of Camel Snus with proposed modified risk advertising in relevant populations. In particular, likely use in sub-groups for whom the advertising was intended (current smokers and tobacco users, especially those not expecting to quit) and sub-groups for whom the advertising was not intended (former and never users of tobacco, and those current users expecting to quit). Evidence that the proposed advertising for Camel Snus preferentially appeals, in terms of likely use, to those who would benefit most from using the product (*e.g.*, current smokers) and has minimal appeal among those whose risk might be increased by using the product (*e.g.*, former and never users of tobacco) would suggest that consumers are likely to comply with instructions for product use necessary to achieve the expected reduction in health risk.

For the likelihood of use studies, respondents rated their interest in purchasing Camel Snus for personal trial. Interest was rated on a 1 – 10 scale, ranging from “Definitely would not purchase” to “Definitely would purchase.” Intent to purchase does not always translate into actual purchase, and does so differently among diverse sub-groups. Thus, the collected intent ratings were used to project likelihood of purchase based on an algorithm empirically derived from studies examining the introduction of new cigarette brands. In this manner, the arbitrarily scaled intent to purchase ratings were translated into projected likelihoods that the sub-groups would actually purchase Camel Snus.

Based on findings from the three likelihood of use studies, exposure to the modified risk advertisements modestly increased current smokers’ interest in Camel Snus ([Section 6.3](#)). Importantly, the advertisements differentially increased interest among current smokers and not among never or former smokers, whose interest was much lower and not increased after viewing the modified risk advertisements. Smokers likely to quit expressed lesser interest in using Camel Snus than did smokers who were not likely to quit, and their interest was not increased after viewing the modified risk advertisements. These findings were largely consistent across the studies, and suggest that advertising modified risk, as proposed, does not attract interest from individuals whose risk might be increased by using Camel Snus (never smokers, former smokers and smokers likely to quit).

Findings from the likelihood of use studies indicating differential appeal for Camel Snus with proposed modified risk advertising among current smokers versus former and never tobacco users, and the consistency of those findings across the three advertising executions, indicate that consumers are likely to comply with instructions for product use necessary to achieve the expected reduction in risk.

3.5.2 Number of pouches of Camel Snus used per day

This section summarizes the available data and information on how consumers actually use Camel Snus in terms of the number of pouches consumed (used) per day. Included are summaries of the information provided by published studies, clinical studies sponsored by RJRT and analyses of survey data ([Table 3.5.2-1](#)). In addition, findings from published studies, as well as clinical studies sponsored by RJRT are discussed in more detail in [Section 3.5.2.1](#). Survey estimates for rates of Camel Snus use among current users are presented in [Section 3.5.2.2](#).

Table 3.5.2-1: Studies of Product Use Rates by Exclusive Camel Snus Users and Dual Users of Camel Snus and Cigarettes

Study	Study Design	Time Point	Product Use Condition	Pouch Size (g)	Pouches per Day ^a	Cigarettes per Day ^a
Blank and Eissenberg 2010	Switching	Day 5	Camel Snus Only	0.4	11.7 (0.8)	NA ^b
CSD0804	Cross-sectional	Product adopters ^c	Camel Snus Only	0.6	5.4 (3.7)	NR ^d
CSD0901	Switching	Day 5	Camel Snus Only	0.6	6.4 (3.0)	NA
CSD0904	Cross-sectional	Product adopters ^e	Camel Snus Only	0.6	3.8 (1.8) ^f	NA
CSD0904	Cross-sectional	Product adopters ^e	Camel Snus Only	0.6	5.4 (3.0) ^g	NA
CSD1010	Cessation	Week 24 – 25	Camel Snus Only	0.6	5.1 (5.4) ^h	NA
Hatsukami <i>et al.</i> 2016	Cessation	Week 6	Camel Snus Only	1.0 ⁱ	5.3 (3.8) ^j	NA
HSD0702	Switching	Week 24 ^k	Dual Use ^l	0.4	8.3 (6.0)	6.8 (6.9)
HSD0702	Switching	Week 24 ^m	Dual Use	0.4	10.2 (6.7)	4.8 (4.3)
O'Connor <i>et al.</i> 2011	Switching	Day 7	Dual Use	0.4	4.7 ⁿ	8.7 ⁿ
CSD0804	Cross-sectional	Product adopters	Dual Use	0.6	2.8 (1.2)	NR
CSD0904	Cross-sectional	Product adopters ^e	Dual Use	0.6 ^o	2.6 (1.8) ^f	15.0 (7.7) ^f
CSD0904	Cross-sectional	Product adopters ^e	Dual Use	0.6	2.4 (2.2) ^g	9.2 (4.2) ^g
CSD0905	Switching	Week 4	Dual Use	0.6	3.5 (2.3)	9.3 (5.2)
CSD1010	Cessation	Week 24 – 25	Dual Use	0.6	5.5 (5.5) ^h	6.0 (3.6) ^h
CSD0901	Switching	Day 5	Dual Use ^p	0.6	3.3 (2.0)	7.6 (2.8)
Hatsukami <i>et al.</i> 2011	Switching	Day 14	Dual Use	0.6 ^q	6 ^r	2 ^r
Burris <i>et al.</i> 2014	Switching ^s	Week 2	Dual Use	NR	5 ^r	17.1
Burris <i>et al.</i> 2014	Switching ^t	Week 2	Dual Use	NR	6 ^r	11.2
Burris <i>et al.</i> 2016	Switching	Week 6	Dual Use	1.0	2.9 (2.1)	NR
Burris <i>et al.</i> 2016	Switching	Week 58	Dual Use	1.0	2.2 (1.2)	NR
Hatsukami <i>et al.</i> 2016	Cessation	Week 6	Dual Use	1.0 ⁱ	5.8 (3.1) ^j	4.4 (4.4) ^j
Kotlyar <i>et al.</i> 2011	Switching	Weeks 2 – 4	Mixed ^u	0.4 and 0.6 ^v	6.9 ^w	19.9 (6.4)
NTBM	Cross-sectional	Product adopters	Mixed	0.6	2.6 – 3.5 ^{w,x}	11.8 ^{w,y}
NTBM	Cross-sectional	Product adopters	Mixed	1.0	3.1 – 3.9 ^{w,z}	11.8 ^{w,y}
Brand Tracker	Cross-sectional	Product adopters	Mixed	0.6 and 1.0 ^{aa}	3.4 ^{w,aa}	12.4 ^{w,bb}
PATH	Longitudinal	Product adopters	Mixed	NR	3.4 ^w	NR

^a Mean (standard deviation)

^b Not applicable

^c ≥ 3-months use of Camel Snus as usual brand

- ^d Not reported
- ^e ≥ 6-months use of Camel Snus as usual brand
- ^f Pre-clinic
- ^g In-clinic (limited opportunities to smoke due to area restrictions and study procedures)
- ^h “Cohort 2” results
- ⁱ Some participants who experienced adverse effects from use of 1.0 g pouch size products were provided with 0.6 g pouches.
- ^j Personal communication
- ^k Intent-to-treat sample
- ^l Concurrent use of Camel Snus and cigarettes
- ^m Per-protocol sample
- ⁿ Single value reported for all “alternative products,” specific use rates (Camel Snus and cigarettes) not specified
- ^o One subject used 1.0 g pouch size
- ^p Subjects limited to a maximum of 40% of their typical cigarettes per day
- ^q Pouch size not declared. Pouch size assignment based on flavor variants tested.
- ^r Determined by inspection of graphical data
- ^s “Snus to cope” group
- ^t “Snus to reduce” group
- ^u Mean value reported included both exclusive Camel Snus users as well as dual users of Camel Snus and cigarettes.
- ^v Camel Snus formulation modified during study period; 17 subjects completed the study using 0.4 g pouches exclusively, the remainder were switched to the new 0.6 g pouches during the study.
- ^w Standard deviation not reported
- ^x Range of means reported for Camel Snus Frost, Mint and Mellow styles
- ^y Single value reported based on all six styles of Camel Snus
- ^z Range of means reported for Camel Snus Robust, Winterchill and Frost Large styles
- ^{aa} Product use rates for all U.S. snus, including Camel Snus Frost, Mint, Mellow, Robust, Winterchill and Frost Large styles reported as a single value
- ^{bb} Cigarette use rate for concurrent use with Camel Snus Frost, Mint, Mellow, Robust, Winterchill and Frost Large styles reported as a single value

3.5.2.1 Use of Camel Snus based on published studies and RJRT clinical studies

The information most relevant to the six Camel Snus styles in this Application (Camel Snus Frost, Camel Snus Frost Large, Camel Snus Mellow, Camel Snus Mint, Camel Snus Robust and Camel Snus Winterchill) is provided by studies that examined use of the 0.6 g and 1.0 g styles (pouch sizes included in this Application). These studies are briefly summarized below.

RJRT sponsored a cross-sectional study ([CSD0804](#), findings published in [Caraway and Chen 2013](#)) that included adult users (product adopters) of Camel Snus styles Original, Frost and Spice (0.6 g pouch size). The baseline mean (\pm standard deviation) use rate among all participants (≥ 3 months use of Camel Snus, as usual brand) was 3.3 ± 1.9 pouches per day. Exclusive Camel snus users (no other tobacco product use) reported a mean use rate of 5.4 ± 3.7 pouches per day, whereas dual users of cigarettes and Camel Snus reported using 2.8 ± 1.2 pouches per day. In terms of product use across tobacco categories, 13.2% of Camel Snus users were exclusive snus users, 49.1% were duals users of both snus and cigarettes and 30.2% were users of snus, cigarettes and at least one other tobacco product. The remaining 7.6% of Camel Snus users reported using snus and another tobacco product other than cigarettes. The vast majority (88.7%) of Camel Snus users reported using one pouch at a time, with the remaining 11.3% using 2 or more pouches simultaneously.

In a 5-day clinical confinement study sponsored by RJRT ([CSD0901](#), findings published in [Krautter et al. 2015](#)), adult cigarettes smokers (≥ 10 cigarettes/day for ≥ 1 year) were switched to one of six conditions, including exclusive use of Camel Snus (Frost and Mellow styles, 0.6 g pouch size). The mean daily use rate for Camel Snus (collected daily) was about 6 pouches (with corresponding standard deviations that ranged from 2 to 3). Adult smokers who were switched to a controlled dual use condition (60% reduction in cigarette use and unlimited Camel Snus use when not smoking) reported a mean daily use rate of about 3 snus pouches per day (standard deviations ranged from 1 to 2).

RJRT clinical study [CSD0904](#) employed a cross-sectional design that included product adopters (used Camel Snus, as usual brand, for ≥ 6 months). The pre-clinic mean use rate (\pm standard deviation) among exclusive Camel Snus users (Frost, Mellow and Winterchill styles, 0.6 g pouch size) was 3.8 ± 1.8 pouches per day, whereas the 24-hour in-clinic mean use rate was 5.4 ± 3.0 pouches per day. Among study participants who used both Camel Snus and cigarettes, the pre-clinic mean use rates were 2.6 ± 1.8 pouches per day for snus and 15.0 ± 7.7 cigarettes per day. The corresponding in-clinic mean use rates were 2.4 ± 2.2 pouches per day for snus and 9.2 ± 4.2 cigarettes per day.

RJRT clinical study [CSD1010](#) employed a 6-month cessation study design, examining use of Camel Snus styles Frost and Mellow (0.6 g pouch size). Among study participants assigned to the Camel Snus only group, the mean (\pm standard deviation) use rate was 5.1 ± 5.4 pouches per day, at Week 24 – 25. For those participants using both Camel Snus and cigarettes, mean use rates were 5.5 ± 5.5 pouches per day and 6.0 ± 3.6 cigarettes per day, at Week 24 – 25.

In a 12-week cessation study ([Hatsukami et al. 2016](#)), adult smokers (≥ 10 cigarettes/day) were randomized to different treatment conditions, including a group switched to Camel Snus styles Robust and Winterchill (1.0 g pouch size). At Week 6, exclusive Camel Snus users reported using 5.3 ± 3.8 pouches per day (mean \pm standard deviation), whereas the use rates among smokers using both Camel Snus and cigarettes were 5.8 ± 3.1 pouches per day and 4.4 ± 4.4 cigarettes per day (personal communication). Analyses correlating the extent of product use with the number of cigarettes smoked suggested that more cigarette use was weakly, and negatively, associated with lower snus use, a correlation that continued through Week 5 of the study.

As part of a clinical study sponsored by RJRT ([CSD0905](#), findings published in [Round et al. 2015](#)), adult cigarette smokers (≥ 7 cigarettes/day) were transitioned from exclusive smoking to reduced smoking plus dual use with Camel Snus styles Frost and Mellow (0.6 g pouch size). Study participants were instructed to reduce their daily cigarette use by 25% during Week 2, 50% during Week 3 and 75% during Week 4. At the end of Week 4, participants had achieved a 59% reduction in cigarette use rate (9.3 ± 5.2 cigarettes/day), and had progressively increased their use rate for Camel Snus to 3.5 ± 2.3 pouches per day.

A multi-site, two-week smoking cessation trial using oral tobacco products was conducted among healthy adult cigarette smokers (≥ 10 cigarettes/day for ≥ 1 year) who were interested in quitting smoking ([Hatsukami et al. 2011](#)). Among participants who chose to use Camel Snus styles Frost or Mellow (0.6 g pouch size), the average product use rate during the 14-day treatment period was about 6 ± 2 pouches per day (\pm standard deviation), as those participants maintained a cigarette use rate of about 1 – 2 cigarettes per day.

A pilot study examining smokeless tobacco use and reduced smoking randomized adults smokers (≥ 10 cigarettes/day) to one of two Camel Snus groups, referred to as ‘Snus to Cope’ and ‘Snus to Reduce’, or a ‘Cigarette Only’ group ([Burris et al. 2014](#)). Smokers randomized to the ‘Snus to Cope’ group were instructed to augment their existing tobacco use with snus to circumvent smoking restrictions, whereas smokers in the ‘Snus to Reduce’ group were instructed to start using snus and purposely smoke fewer cigarettes. At the end of the 3-week study, the ‘Snus to Cope’ and ‘Snus to Reduce’ groups reported declines in cigarette use rates of 18.4% and 37.6%, respectively, with both groups reporting an average use rate for Camel Snus of 5 – 6 pouches per day. For the ‘Cigarettes Only’ group, cigarette use rate increased by 4.3% over the course of the study.

Based on a longitudinal study design, adult cigarette smokers (≥ 10 cigarettes/day) not intending to quit smoking in the next month were randomized to receive free Camel Snus styles Frost or Winterchill (1.0 g pouch size) for 6 weeks, and their tobacco use patterns were followed for one year ([Burris et al. 2016](#)). Reported use rates (mean \pm standard deviation) for Camel Snus were generally stable across time, from the end of free product provision to the end of the one-year follow-up, *i.e.*, 2.9 ± 2.1 , 2.8 ± 1.7 , 2.5 ± 1.0 and 2.2 ± 1.2 pouches per day at Week 6, Week 10, Week 32 and Week 58. Corresponding use frequencies, or days used in the past week, were also stable, *i.e.*, 4.0 ± 2.4 , 4.3 ± 2.4 , 3.8 ± 2.3 and 3.2 ± 2.2 , respectively. Study participants’ use of snus was generally concurrent with continued smoking throughout

the follow-up period, with no data provided on cigarette use frequency or rate. Nonetheless, dual use of cigarettes and Camel Snus did decrease from 47.5% (Week 6) to 4.2% (Week 58).

Finally, a switching study was conducted to determine if smokers who were interested in quitting were willing to switch to oral smokeless tobacco or nicotine products ([Kotlyar et al. 2011](#)). During 4 weeks of product use, participants in the Camel Snus group (Original, Frost and Spice styles; 0.4 g and 0.6 g pouch sizes) reported using an average of 6.9 pouches per day. The baseline cigarette use rate among study participants assigned to the Camel Snus group was 19.9 ± 6.4 cigarettes per day. During the 4-week treatment period, smokers assigned to this group were largely able to comply with the study requirement of no cigarette use.

Information from studies that have examined use of the Camel Snus styles in this Application (0.6 g and 1.0 g pouch sizes) indicates that consumers generally report using between 2 and 6 pouches per day. Moreover, findings from these studies suggest that smokers are able to achieve substantial reductions in cigarette use at these Camel Snus use rates.

3.5.2.2 Use of Camel Snus based on analyses of survey data

Descriptive analyses were conducted using data from the National Tobacco Behavior Monitor (NTBM; survey period, January 2013 to March 2016; n=94,678) ([Camel Snus Product Use Report](#)). These analyses examined use rates (uses/day on days used during the past week), use frequencies (days used during the past week) and tobacco use behavior patterns (product use across tobacco types, including concurrent use of cigarettes) among adult current users of Camel Snus, non-Camel snus and other types of smokeless tobacco (loose moist snuff, portioned moist snuff and loose leaf chew tobacco). Current users of the different smokeless tobacco product types were identified based on self-reported past-30-day (P30D) use, or having used the product type (and brand, where applicable) at least one day during the past 30 days.

Confirmatory analyses were conducted among adult current users of Camel Snus and other smokeless tobacco product types based on data from RJRT's Consumer Brand Tracker (Brand Tracker) and, in some instances, the National Institutes of Health (NIH) and Food and Drug Administration's (FDA) Population Assessment of Tobacco and Health Study (PATH). Current users of the different product types in Brand Tracker and PATH were identified based on self-reported past-7-day (P7D) and P30D use, respectively.

3.5.2.2.1 Tobacco use rate among current Camel Snus users is generally similar to use rates for other smokeless tobacco products

NTBM provides adult respondent data on tobacco use rates (uses per day on days used during the past week) among current users across a number of smokeless tobacco types, which can be further stratified by usual brand and style. The predominant use behavior pattern among smokeless tobacco users is dual/poly use of other combustible and/or non-combustible tobacco products ([Section 3.5.2.2.3](#)). Thus, the analyses of data from NTBM include all P30D users of snus (Camel Snus as usual brand, "Camel Snus"; and, usual brand not Camel Snus, "non-Camel snus"), loose moist snuff, portioned moist snuff and loose leaf chew tobacco.

Table 3.5.2-2 presents tobacco use rates among P30D users of Camel Snus compared to users of non-Camel snus and other smokeless tobacco product types. Descriptive analyses based on data from NTBM indicate that a majority of P30D users of Camel Snus (57.3%), non-Camel snus (58.3%), portioned moist snuff (55.9%) and loose leaf chew tobacco (59.6%) report a rate of 1 – 2 uses per day. Loose moist snuff users are less likely to report a low use rate (40.5%, 1 – 2 uses/day), and more likely to report 7 or more uses per day (20.6%) ([Camel Snus Product Use Report](#)).

Table 3.5.2-2: Tobacco Use Rates among P30D Camel Snus and Other Smokeless Tobacco Users

Tobacco Product Type [†]	Camel Snus	Non Camel Snus	Loose Moist Snuff	Portioned Moist Snuff	Loose Leaf Chew
<i>Weighted count</i> [^]	425	789	2284	1055	944
Tobacco Use Rate (uses/day)					
1 use/d¹	35.2	37.2	22.2	36.7	36.7
<i>weighted count</i> ²	150	293	507	387	347
2 uses/d	22.1	21.1	18.3	19.2	22.9
<i>weighted count</i>	94	166	417	202	216
3-4 uses/d	21.1	20.8	21.3	18.7	19.5
<i>weighted count</i>	90	164	486	198	184
5-6 uses/d	11.3	13.9	17.7	12.7	11.0
<i>weighted count</i>	48	110	404	134	104
7+ uses/d	10.3	7.0	20.6	12.7	9.9
<i>weighted count</i>	44	55	470	134	94
Mean, uses/day	3.2	2.9	4.5	3.4	3.1
95% CI	(2.9, 3.4)	(2.8, 3.1)	(4.4, 4.7)	(3.2, 3.6)	(2.9, 3.2)

[†] Respondents reporting use of tobacco product on one or more days during past 30 days; and, Camel Snus, used most often and considered as usual brand.

[^] Weighted counts reduced due to non-response on question for product use rate; estimates for percentages within categories and means based on available data (exclude non-responses).

¹ Bolded values in table represent percentages within categories (some columns may not add to 100% due to rounding/weighting), and means with 95% confidence intervals (95% CI).

² Italicized values represent weighted counts.

Estimated mean use rates are generally consistent among P30D users of Camel Snus (mean uses/day: 3.2, 95% CI: 2.9 – 3.4), non-Camel snus (2.9, 2.8 – 3.1), portioned moist snuff (3.4, 3.2 – 3.6) and loose leaf chew tobacco (3.1; 2.9 – 3.2). The mean use rate among loose moist snuff users is comparatively higher (4.5, 4.4 – 4.7) ([Table 3.5.2-2](#)). Stratification of P30D users of Camel Snus by the six styles in this Application (Frost, Mint, Mellow, Robust, Winterchill and Frost Large) provides comparable estimates of mean rates of use, with a somewhat narrow range of 2.6 to 3.9 uses per day on days used ([Table 3.5.2-3](#)).

Table 3.5.2-3: Tobacco Use Rates among P30D Camel Snus Users (by brand style)

Camel Snus Style [†]	Frost	Mint	Mellow	Robust	Winterchill	Frost Large
<i>Weighted count</i> [^]	185	92	65	26	36	20
Mean, uses/day	3.2	2.6	3.5	3.1	3.9	3.2
95% CI	(2.8, 3.6)	(2.2, 3.1)	(2.8, 4.2)	(2.5, 3.6)	(2.9, 4.9)	(2.0, 4.4)

[†] Respondents reporting use of tobacco product on one or more days during past 30 days; and, Camel Snus, used most often and considered as usual brand.

[^] Weighted counts reduced due to non-response on question for product use rate; estimates for percentages within categories and means based on available data (exclude non-responses).

Descriptive analyses based on data from Brand Tracker indicate that, similar to findings from NTBM, the vast majority of P7D users of snus² report a product use rate of 1 – 5 uses per day (84.7%); 12.2% and 2.6% of users report rates of 6 – 10 and 11 or more uses per day, respectively ([Camel Snus Product Use Report](#)). Product use rates were comparatively higher among P7D users of moist snuff, with 68.2%, 24.1% and 7.2% reporting use rates of 1-5, 6-10 and 11 or more uses per day, respectively. Higher use rates among current moist snuff users were also reflected in higher mean estimates (mean uses/day: 5.1, 95% CI: 5.0 – 5.2 versus 3.4, 95% CI: 3.3 – 3.5 for current snus users).

Publicly available data from NIH/FDA’s PATH provide a relatively small sample of adult P30D Camel Snus users. Nonetheless, this sample is sufficient to assess mean use rate (mean number of uses per day on days used during the past month) among current Camel Snus users. Data from PATH indicate that adult P30D Camel Snus users report a mean use rate of 3.4 uses per day, nearly identical to estimates provided by NTBM.

Collectively, data from all three surveys indicate that the use rate for Camel Snus is generally similar to that for other smokeless tobacco products, with the mean use rate among current users of Camel Snus being slightly above 3 uses per day on days used.

3.5.2.2.2 Tobacco use frequency among current Camel Snus users is generally similar to use frequencies for other smokeless tobacco products

NTBM provides adult respondent data on tobacco use frequencies (number of days used during the past week) among current users across a number of smokeless tobacco product types, which can be further stratified by usual brand and style. The predominant use behavior pattern among smokeless tobacco users is dual/poly use of other combustible and/or non-combustible tobacco products ([Section 3.5.2.2.3](#)). Thus, the analyses of data from NTBM include all P30D users of snus (Camel Snus as usual brand, “Camel Snus”; and, usual brand not Camel Snus, “non-Camel snus”), loose moist snuff, portioned moist snuff and loose leaf chew tobacco.

² For Brand Tracker, ‘snus’ examined as tobacco product type, based on incomplete data for usual brand among P7D users; and, ‘loose moist snuff’ and ‘portioned moist snuff’ combined into single category, ‘moist snuff’, due to questionnaire structure.

Table 3.5.2-4 presents tobacco use frequencies among P30D users of Camel Snus compared to users of non-Camel snus and other smokeless tobacco product types. Number of days used per week is categorized as ‘near weekly/weekly’ (0 – 1 days/week)³, ‘more than weekly’ (2 – 5 days/week) and ‘near daily/daily’ (6 – 7 days/week). Descriptive analyses based on data from NTBM indicate that the vast majority of adult P30D users of Camel Snus (85.4%), non-Camel snus (88.4%), portioned moist snuff (84.6%) and loose leaf chew tobacco (88.2%) report less than ‘near daily/daily’ use (6 – 7 days/week). The proportion of loose moist snuff users who report less than ‘near daily/daily’ use is comparatively lower (65.9%) (Camel Snus Product Use Report).

Table 3.5.2-4: Tobacco Use Frequencies among P30D Camel Snus and Other Smokeless Tobacco Users

Tobacco Product Type [†]	Camel Snus	Non Camel Snus	Loose Moist Snuff	Portioned Moist Snuff	Loose Leaf Chew
<i>Weighted count</i>	555	968	2625	1322	1212
Tobacco Use Frequency (days/week)					
0-1 d/wk (%)¹	46.2	43.9	28.3	45.4	46.9
<i>weighted count²</i>	257	425	743	601	569
2-5 d/wk (%)	39.2	44.5	37.6	39.2	41.3
<i>weighted count</i>	218	430	987	519	500
6-7 d/wk (%)	13.9	11.7	34.1	15.3	11.8
<i>weighted count</i>	77	113	894	203	143
Mean, days/week	2.4	2.4	3.7	2.5	2.4
95% CI	(2.3, 2.6)	(2.3, 2.6)	(3.7, 3.8)	(2.4, 2.7)	(2.2, 2.5)

[†] Respondents reporting use of tobacco product on one or more days during past 30 days; and, Camel Snus, used most often and considered as usual brand (and style).

¹ Bolded values in table represent percentages within categories (some columns may not add to 100% due to rounding/weighting) and/or means with 95% confidence intervals (95% CI).

² Italicized values represent weighted counts.

Estimated mean use frequencies are consistent among P30D users of Camel Snus (mean days/week: 2.4, 95% CI: 2.3 – 2.6), non-Camel snus (2.4, 2.3 – 2.6), portioned moist snuff (2.5, 2.4 – 2.7) and loose leaf chew tobacco (2.4, 2.2 – 2.5). The mean use frequency among loose moist snuff users is comparatively higher (3.7, 3.7 – 3.8), but still within the ‘more than weekly’ categorization (2 – 5 days/week) (Table 3.5.2-4). Stratification of P30D users of Camel Snus by the six styles in this Application (Frost, Mint, Mellow, Robust, Winterchill and Frost Large) provides comparable estimates of mean use frequencies, with a narrow range of 2.2 to 3.0 days used per week (Table 3.5.2-5).

³ NTBM respondent data include P30D users of smokeless tobacco products; hence, ‘near weekly/weekly’ category includes range of ‘0 – 1 days used during the past week’, as not all P30D users reported use during past week.

Table 3.5.2-5: Tobacco Use Frequencies among P30D Camel Snus Users (by brand style)

Camel Snus Style[†]	Frost	Mint	Mellow	Robust	Winterchill	Frost Large
<i>Weighted Count</i>	291	129	86	35	57	35
Mean, days/week	2.4	2.2	2.6	2.5	3.0	2.5
95% CI	(2.1, 2.6)	(1.9, 2.5)	(2.2, 3.0)	(1.8, 3.2)	(2.3, 3.7)	(1.5, 3.4)

[†] Respondents reporting use of tobacco product on one or more days during past 30 days; and, Camel Snus, used most often and considered as usual brand (and style).

Descriptive analyses based on data from Brand Tracker indicate that the vast majority of P7D users of snus⁴ and loose leaf chew do not report a product use frequency categorized as ‘near daily/daily’ (78.8% and 78.7%, respectively).⁵ In contrast, 51.4% of current loose moist snuff users report ‘near daily/daily’ use ([Camel Snus Product Use Report](#)). Estimated mean use frequencies are consistent among P7D users of snus and loose leaf chew tobacco (mean days/week: 3.5, 95% CI: 3.4 – 3.5 and 3.3, 95% CI: 3.2 – 3.4, respectively). Mean use frequency among loose moist snuff users is comparatively higher (5.0, 4.9 – 5.0), but still within the ‘more than weekly’ (2 – 5 days/week) categorization.

Publicly available data from NIH/FDA’s PATH provide a relatively small sample of adult P30D Camel Snus users. Nonetheless, this sample is sufficient to assess mean use frequency (mean number of days used during the past month) among current Camel Snus users. Data from PATH indicate that P30D Camel Snus users report a mean use frequency of 17.0 days per month (95% CI: 14.7 – 19.3; n=101, weighted), or slightly more than 4 days per week.

Collectively, data from all three surveys indicate that the use frequency for Camel Snus is generally similar to that for other smokeless tobacco products, with the mean use frequency among current users of Camel Snus being about 2 to 4 days per week.

3.5.2.2.3 Tobacco use behavior patterns among current Camel Snus users are generally similar to use patterns for other smokeless tobacco products

With regard to tobacco use behavior patterns among adult current users across a number of smokeless tobacco product types, descriptive analyses based on data from NTBM indicate that the vast majority of P30D users of Camel Snus (92.8%), non-Camel snus (96.3%), portioned moist snuff (93.3%), loose leaf chew (92.4%) and loose moist snuff (77.4%) are dual/poly users

⁴ For Brand Tracker, ‘snus’ examined as tobacco product type, based on incomplete data for usual brand among P7D users; and, ‘loose moist snuff’ and ‘portioned moist snuff’ combined into single category, ‘moist snuff’, due to questionnaire structure.

⁵ Brand Tracker data includes P7D users of smokeless tobacco products; hence, ‘near weekly/weekly’ category limited to ‘1 day used during the past week’, as all P7D users must have reported use during past week; the remaining categories for use frequency are as described for NTBM, ‘more than weekly’ (2 – 5 days/week) and ‘near daily/daily’ (6 – 7 days/week).

of other combustible and/or non-combustible tobacco products ([Table 3.5.2-6; Camel Snus Product Use Report](#)).

Table 3.5.2-6: Tobacco Use Behavior Patterns among P30D Camel Snus and Other Smokeless Tobacco Users

Tobacco Product Type [†]	Camel Snus	Non Camel Snus	Loose Moist Snuff	Portioned Moist Snuff	Loose Leaf Chew
<i>weighted count</i>	555	968	2625	1322	1212
Use Behavior Category					
solo user (%) ¹	7.2	3.7	22.6	6.7	7.6
<i>weighted count</i> ²	40	35	594	89	92
dual use w/ cigarettes (%)	8.6	4.1	6.9	3.4	1.8
<i>weighted count</i>	48	40	182	45	22
dual use w/ combustibles* (%)	5.0	2.9	5.7	3.9	2.5
<i>weighted count</i>	28	28	149	52	31
dual/poly use w/ combustibles and non-combustibles (%)	68.1	80.5	54.7	76.3	77.6
<i>weighted count</i>	378	779	1436	1008	940
dual/poly use w/ non-combustibles (%)	11.0	8.8	10.0	9.7	10.5
<i>weighted count</i>	61	86	263	128	128

[†] Respondents reporting use of tobacco product on one or more days during past 30 days.

* This includes dual users with cigarettes and/or another combustible product that is typically smoked like cigarettes, such as roll-your-own cigarettes, little cigars and cigarillos - but who are **not** included within the 'dual use w/ cigarettes' category (only use smokeless product and cigarettes).

¹ Bolded values in table represent percentages within categories; some columns may not add to 100% due to rounding/weighting.

² Italicized values represent weighted counts.

Descriptive analyses based on data from Brand Tracker indicate that an estimated 3.5% of snus users (n=5,870; all brands)⁶, 22.7% of moist snuff users (n=9,297; loose and portioned product combined) and 6.1% of loose leaf chew users (n=7,650) report being exclusive product users ([Camel Snus Product Use Report](#)). These data are generally consistent with findings from NTBM in terms of indicating that the predominant use behavior pattern among current smokeless tobacco users (including snus users) is dual/poly use of other tobacco product types.

Publicly available data from NIH/FDA's PATH provide a relatively small sample of adult P30D Camel Snus users. Nonetheless, this sample is sufficient to assess the proportions of current users who report being exclusive product users, as compared to dual/poly users of other combustible and/or non-combustible tobacco products. Data from PATH indicate that among P30D users of Camel Snus (n=103), an estimated 15.5% report being exclusive product users, with the vast majority (84.5%) being dual/poly users of other combustible and/or non-combustible tobacco products ([Camel Snus Product Use Report](#)). These data are generally

⁶ For Brand Tracker, 'snus' examined as tobacco product type, based on incomplete data for usual brand among P7D users; and, 'loose moist snuff' and 'portioned moist snuff' combined into single category, 'moist snuff', due to questionnaire structure.

consistent with findings from NTBM, in terms of indicating the predominant use behavior pattern among current Camel Snus users is dual/poly use of other product types.

3.5.2.2.4 Demographic characteristics among current Camel Snus users are generally similar to those of other smokeless tobacco products

Descriptive analyses based on data from NTBM indicate that demographic characteristics among adult current users of Camel Snus are generally similar to those for current users of other smokeless tobacco product types, including users of loose moist snuff and loose leaf chew tobacco ([Camel Snus Product Use Report](#)). Specifically, adult P30D users of Camel Snus, as well as other types of smokeless tobacco, are predominantly between the ages of 25 and 49 years (69.2 – 75.2%), male (80.8 – 85.7%), Caucasian (52.3 – 65.2%) and well educated (63.8 – 69.4% report at least some college). A much smaller proportion of adult P30D users of Camel Snus, as well as other types of smokeless tobacco, are young adults age 18 – 24 years (13.4 – 17.5%); less than 10% are African American and less than 30% (18.8 – 28.4%) are Hispanic. These findings were confirmed through the analysis of a secondary data source, Brand Tracker ([Camel Snus Product Use Report](#)).

3.5.3 Concurrent use of Camel Snus and other products containing nicotine or tobacco

This section summarizes the available data on concurrent use of Camel Snus and other products that contain nicotine or tobacco. Information provided by the published literature and clinical studies sponsored by RJRT is summarized in [Table 3.5.2-1](#) and discussed in [Section 3.5.2.1](#). This section includes additional information from one of the clinical studies sponsored by RJRT ([CSD0904](#)), as well as a summary of the information provided by analyses of survey data.

3.5.3.1 Concurrent use of Camel Snus and cigarettes based on clinical study CSD0904

Information from a clinical study of product adopters ([CSD0904](#), sponsored by RJRT) indicates that dual users of Camel Snus and cigarettes reported smoking fewer cigarettes per day compared to exclusive cigarette smokers, with reductions of up to 25% ([Table 3.5.3-1](#); for additional details on RJRT's clinical studies, see [Section 6.1.2](#)).

Table 3.5.3-1: Tobacco Use Rates among Camel Snus Product Adopters

User Group	Time Point	Pouches/Day		Cigarettes/Day	
		(Mean \pm SD)	Min, Max	(Mean \pm SD)	Min, Max
Exclusive Cigarettes	Pre-Clinic Use			18 \pm 7 cigarettes	(6, 47)
	In-Clinic Use			12 \pm 4 cigarettes	(4, 27)
Dual Use Camel Snus + Cigarettes	Pre-Clinic Use	2 \pm 2 pouches	(1, 12)	15 \pm 8 cigarettes	(4, 43)
	In-Clinic Use	2 \pm 2 pouches	(0, 12)	9 \pm 4 cigarettes	(0, 21)
Exclusive Camel Snus	Pre-Clinic Use	4 \pm 2 pouches	(1, 8)		
	In-Clinic Use	5 \pm 3 pouches	(1, 15)		

3.5.3.2 Concurrent use of Camel Snus with other products based on survey research

NTBM provides adult respondent data on use behavior patterns (product use across tobacco categories) among current cigarette users, which can be stratified based on concurrent use of other tobacco products (including Camel Snus). Descriptive analyses were conducted to examine both rate and frequency of cigarette use among P30D exclusive cigarette users and P30D users of both cigarettes and Camel Snus (as usual brand).

Brand Tracker data were evaluated to confirm findings from NTBM. Brand Tracker also provides adult respondent data on use behavior patterns (product use across tobacco categories) among current cigarette users that can be stratified based on concurrent use of other tobacco products (including Camel Snus).

3.5.3.2.1 Concurrent use of Camel Snus among smokers reduces cigarette use rate

Based on data from NTBM (survey period from January 2013 to March 2016), cigarette use rate was examined among adult P30D cigarette users who report exclusive use of cigarettes compared to those who report use of both cigarettes and Camel Snus ([Table 3.5.3-2; Camel Snus Product Use Report](#)). Descriptive analyses indicate that P30D smokers who are exclusive cigarette users report a mean use rate of 12.9 (95% CI: 12.7 – 13.1) cigarettes per day, with 69.5% of exclusive users smoking 7 or more cigarettes per day.

Table 3.5.3-2: Cigarette Use Rate among P30D Cigarette Users

Tobacco Use Pattern[†]	Cigarettes	Cigarettes with Camel Snus
<i>Weighted count</i>	<i>12744</i>	<i>409</i>
Cigarette Use Rate (cig/d)		
0-2 cig/d (%)¹	9.0	24.0
<i>weighted count²</i>	<i>1149</i>	<i>98</i>
3-4 cig/d (%)	8.6	5.8
<i>weighted count</i>	<i>1090</i>	<i>24</i>
5-6 cig/d (%)	12.9	10.6
<i>weighted count</i>	<i>1644</i>	<i>43</i>
7+ cig/d (%)	69.5	59.7
<i>weighted count</i>	<i>8862</i>	<i>244</i>
Mean, uses/day	12.9	11.8
95% CI	(12.7, 13.1)	(10.9, 12.8)

[†] Respondents reporting use of tobacco product on one or more days during past 30 days; and, Camel Snus, used most often and considered as usual brand.

¹ Bolded values in table represent percentages within categories (some columns may not add to 100% due to rounding/weighting), and means with 95% confidence intervals.

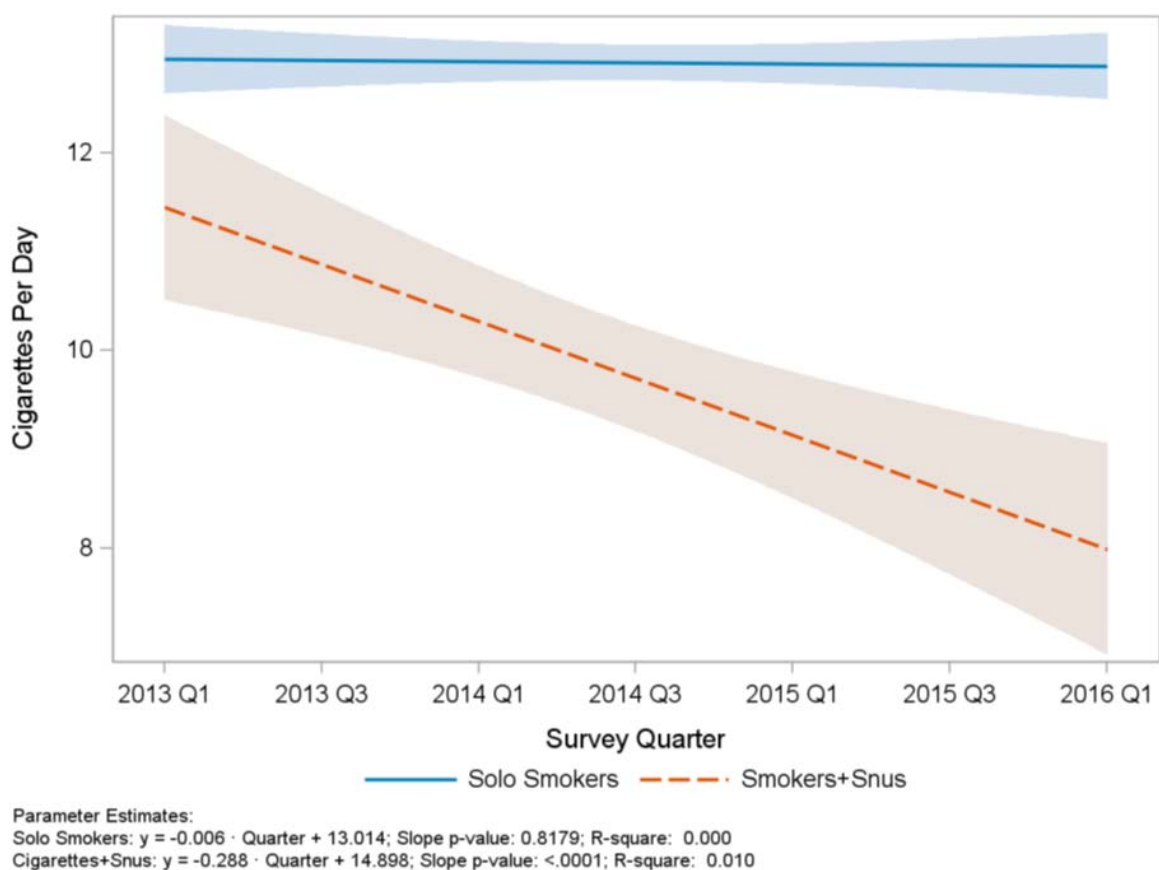
² Italicized values represent weighted counts.

P30D smokers who use both cigarettes and Camel Snus report a comparatively lower mean use rate of 11.8 (95% CI: 10.9 – 12.8) cigarettes per day, with a smaller proportion of dual users smoking 7 or more cigarettes per day (59.7%). The proportion of dual users of cigarettes and Camel Snus who report smoking 0 – 2 cigarettes per day⁷ is more than double the proportion of exclusive cigarette users who report the same low use rate (24.0% versus 9.0%, respectively).

Figure 3.5.3-1 presents findings from a weighted linear regression analysis, comparing cigarette use rates among respondents who report exclusive cigarette use and those who use both cigarettes and snus ([Camel Snus Product Use Report](#)). Cigarette use rate among exclusive users remained fairly constant during the period of January 2013 to March 2016, while use rate among those who use both cigarettes and Camel Snus decreased, with a significant downward trend in number of cigarettes smoked per day on days used during the past week. By the last survey quarter, the predicted difference in cigarette use rate among exclusive users and those who use both cigarettes and snus increased from approximately 1 to approximately 5 cigarettes per day, with greater use observed for exclusive cigarette smokers.

⁷ NTBM respondent data includes past-30-day users of cigarettes; hence, the lowest use rate category includes a range of '0 - 2 cigarettes per day', as not all P30D users reported use during the past week.

Figure 3.5.3-1: Trends for Cigarette Use Rate among P30D Cigarette Users⁸



Based on data from Brand Tracker, use rate was examined among P7D smokers who report exclusive cigarette use and those who use both cigarettes and Camel Snus ([Camel Snus Product Use Report](#)). Respondents categorized as exclusive cigarette users report a mean use rate of 13.3 (95% CI: 13.2 – 13.4) cigarettes per day, with 50.4% of these smokers using 1 – 10 cigarettes per day. Respondents categorized as using both cigarettes and Camel Snus report a comparatively lower mean use rate of 12.4 (95% CI: 11.7 – 13.2) cigarettes per day, with a slightly higher proportion of dual users smoking 1 – 10 cigarettes per day (55.6%).

Thus, data from both NTBM and Brand Tracker indicate that current users of both cigarettes and Camel Snus report a lower cigarette use rate (number of cigarettes smoked per day on days smoked during the past week) than exclusive cigarette smokers.

⁸ A relationship exists between the individual point estimates in Table 3.5.8 for the means and the regression plots presented in Figure 3.5.1. The intercepts, where the lines crosses the y-axis, approximately equal the point estimates.

3.5.3.2.2 Concurrent use of Camel Snus among smokers reduces cigarette use frequency

Based on data from NTBM (survey period from January 2013 to March 2016), cigarette use frequency was examined among adult P30D cigarette users who report exclusive use of cigarettes compared to those who report using both cigarettes and Camel Snus ([Table 3.5.3-3; Camel Snus Product Use Report](#)). Descriptive analyses indicate that the vast majority of exclusive cigarette users report a use frequency that is categorized as ‘near daily/daily’ (6 – 7 days/week; 76.5%), with less than 10% of these smokers reporting ‘near weekly/weekly’ use (0 – 1 days/week)⁹. Mean use frequency among exclusive cigarette users was estimated to be 5.9 days per week.

Table 3.5.3-3: Cigarette Use Frequency among P30D Cigarette Users

Tobacco Use Pattern[†]	Cigarettes	Cigarettes with Camel Snus
<i>Weighted count</i>	<i>13455</i>	<i>433</i>
Cigarette Use Frequency (d/wk)		
0-1 d/wk (%)¹	8.4	19.6
<i>weighted count²</i>	<i>1134</i>	<i>85</i>
2-5 d/wk (%)	15.1	25.3
<i>weighted count</i>	<i>2030</i>	<i>109</i>
6-7 d/wk (%)	76.5	55.1
<i>weighted count</i>	<i>10292</i>	<i>239</i>
Mean, days/week	5.9	4.8
95% CI	(5.9, 5.9)	(4.6, 5.0)

[†] Respondents reporting use of tobacco product on one or more days during past 30 days; and, Camel Snus, used most often and considered as usual brand.

¹ Bolded values in table represent percentages within categories (some columns may not add to 100% due to rounding/weighting), and means with 95% confidence intervals (95% CI).

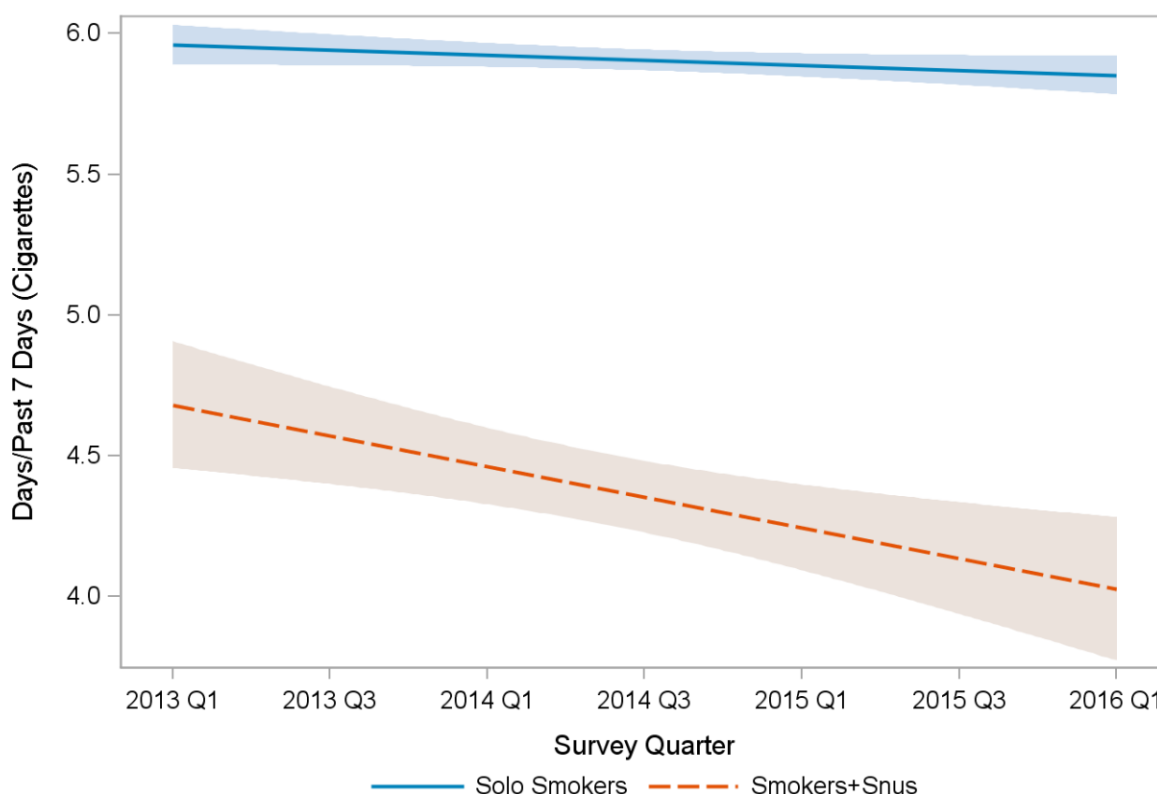
² Italicized values represent weighted counts.

A lower proportion of P30D users of both cigarettes and Camel Snus report a cigarette use frequency categorized as ‘near daily/daily’ (55.1%), with nearly 20% of dual users reporting ‘near weekly/weekly’ use. In addition, mean use frequency is comparatively lower (4.8 days/week, 95% CI: 4.6 – 5.0) among those who report using both cigarettes and Camel Snus.

⁹ NTBM respondent data includes past-30-day users of cigarettes; hence, the lowest use frequency category includes range of ‘0 – 1 days used during the past week’, as not all P30D users reported use during the past week.

Figure 3.5.3-2 presents findings from a weighted linear regression analysis, comparing cigarette use frequencies among respondents who report exclusive cigarette use and those who use both cigarettes and snus ([Camel Snus Product Use Report](#)). Cigarette use frequency among exclusive users remained fairly constant during the period of January 2013 to March 2016, while use frequency among those who use both cigarettes and snus decreased slightly, with a significant downward trend in the number of days smoked during the past week. By the last survey quarter, the predicted nominal difference in cigarette use frequency among exclusive users and those who use both cigarettes and snus approximately doubled (*i.e.*, to about 2 days per week).

Figure 3.5.3-2: Trends for Cigarette Use Frequency among P30D Cigarette Users¹⁰



Parameter Estimates:

Solo Smokers: $y = -0.009 \cdot \text{Quarter} + 6.0667$; Slope p-value: 0.0738; R-square: 0.000

Cigarettes+Snus: $y = -0.054 \cdot \text{Quarter} + 5.3346$; Slope p-value: 0.0017; R-square: 0.006

Based on data from Brand Tracker, use frequency was examined among adult P7D smokers who report exclusive cigarette use and those who use both cigarettes and Camel Snus ([Camel Snus Product Use Report](#)). Respondents categorized as exclusive cigarette users report a mean use frequency of 6.6 (95% CI: 6.59 – 6.61) days smoked during the past week, with 89.9% of these users reporting ‘near daily/daily’ use (6 – 7 days/week). Respondents categorized as using both

¹⁰ A relationship exists between the individual point estimates in Table 3.5.9 for the means and the regression plots presented in Figure 3.5.2. The intercepts, where the lines cross the y-axis, approximately equal the point estimates.

cigarettes and Camel Snus report a comparatively lower mean use frequency for cigarettes of 6.0 (95% CI: 5.89 – 6.15) days smoked during the past week, with a smaller proportion of dual users reporting 'near daily/daily' use (73.8%). The proportion of dual users of cigarette and Camel Snus users who report 'more than weekly' cigarette use (2 – 5 days/week) is more than double the proportion of cigarette only users who report the same lower use frequency (22.8% versus 8.3%, respectively).

Thus, data from both NTBM and Brand Tracker indicate that current users of both cigarettes and Camel Snus report a lower cigarette use frequency (number of days smoked during the past week) than exclusive cigarette users.