

6.2 Camel Snus Modified Risk Advertising: Comprehension and Perceptions among Tobacco Users and Non-Users

6.2.1 Background

Consumers should understand modified risk messages regarding an MRTP. Accordingly, the FDA's MRTPA Draft Guidance states that applications "must contain evidence to show that the advertising and labeling concerning modified risk products enable the public to comprehend the information concerning modified risk and to understand the relative significance of such information in the context of total health and in relation to all of the diseases and health-related conditions associated with the use of tobacco products" ([TCA Section 911\(h\)\(1\)](#); [FDA MRTPA Draft Guidance 2012, pp. 5, 20](#)). Such evidence will serve to inform FDA's evaluation of the effects of modified risk advertising for tobacco products on consumer understanding and perceptions. In accordance with the TCA and FDA's MRTPA Draft Guidance, RJRT conducted three comprehension and perceptions studies to assess the effects of the proposed modified risk advertising for Camel Snus on current tobacco users' and non-users' (including former users and never users) understanding and perceptions.

6.2.2 The Proposed Modified Risk Advertising

RJRT developed and tested three different advertising executions with modified risk messaging. The three comprehension and perceptions studies included advertisements that differed slightly in the modified risk messaging they contained, but shared a common objective and graphical approach. Full study reports, study protocols, and raw data for each of the three executions are submitted with this Application.

In addition to the four government-mandated warning label statements, RJRT's proposed modified risk advertisements include the following additional health-related information:

- Camel Snus is addictive.
- No tobacco product is safe.
- Adults who do not currently use tobacco or have quit using tobacco should not start.
- Minors and pregnant women should not use tobacco products.
- The best option for smokers concerned about health risks is to quit smoking.

Additional product information not related to risk is also included:

- What Camel Snus is
- How Camel Snus differs from more familiar smokeless tobacco products

- How to use Camel Snus

6.2.3 Comprehension and Perceptions Study Objectives

The comprehension and perceptions studies assessed consumer understanding of the following messages or communication objectives:

- Smokers switching completely to Camel Snus can reduce the risk of certain smoking-related diseases enumerated in the proposed advertisement.
- Camel Snus still bears some health risks (even for diseases where risk is reduced).
 - Camel Snus does not reduce the risk of all other smoking-related diseases.
 - Camel Snus does not eliminate all risk to overall health.
- The modified risk claims made for Camel Snus do not necessarily apply to other smokeless tobacco products.
- Camel Snus is not a safer alternative to nicotine-based smoking cessation medications.
- Camel Snus is not a safer alternative to quitting smoking completely.
- Quitting smoking is the best choice for smokers.
- Camel Snus is addictive.
- Those who do not use tobacco products should not use Camel Snus.

Details of the comprehension and perceptions study for each proposed modified risk advertising execution are summarized in the sections that follow.

6.2.4 Camel SNUS Modified Risk Messaging: Comprehension and Perceptions among Tobacco Users and Non-Users: First Execution of Consumer Testing

6.2.4.1 Study Methods

Sample

An online study was conducted with a sample of 8,404 U.S. adults who, based on age (typically 18+) were legally eligible to purchase tobacco in their state of residence. The sample was drawn randomly from the Research Now online panel of approximately three million individuals in the U.S. Quota sampling was done to obtain approximately 2,500 respondents each in three tobacco user groups of interest (current tobacco users, former tobacco users, and never tobacco users, described below). Quota sampling was also used to maximize representativeness with respect to gender, age, race/ethnicity, education, and geographic region. Sampling was done to ensure a

minimum of 100 respondents in other subgroups of interest, including those with limited health literacy, ethnic minorities, and white males (who are the primary users of smokeless tobacco (USDHHS 2014)). Young adults ages 18-24 were analyzed as a subgroup, as a proxy for those under legal purchase age.

The three tobacco user groups of interest were as follows:

1. *Current tobacco users* (n=2,497), defined as those who met historical usage thresholds for at least one tobacco product (*i.e.*, smoked at least 100 cigarettes in lifetime [Bondy *et al.* 2009], or ever fairly regularly used any other tobacco product), and used tobacco “every day” or “some days” at the time of the study;
2. *Former tobacco users* (n=2,477), defined as those who met historical usage thresholds for at least one tobacco product, but did not use tobacco at all at the time of the study; and
3. *Never tobacco users* (n=2,492), defined as those who reported having never used tobacco, even once or twice.

An additional sample of experimental tobacco users (n=938) was surveyed to capture those who have used tobacco products but have not become established users. The final sample (n=8,404) was weighted to match the U.S. population in terms of gender, age, race/ethnicity, education, and geographic region. A detailed description of the sampling plan and weighting is available in the study protocol ([Protocol Identifier: RO-BR-2014-02 Camel Snus Modified Risk Messaging: Comprehension and Perceptions among Tobacco Users and Non-Users](#)) and the final study report ([Camel SNUS Modified Risk Messaging: Comprehension and Perceptions among Tobacco Users and Non-Users – First Execution of Consumer Testing – Amended Final Report](#)), respectively.

Additional subgroups

Consistent with the tobacco literature (CDC 1994), established tobacco users (current and former users) were identified based on having achieved a sufficiently high level of use to qualify as established users. For example, based on the literature (Bondy *et al.* 2009), those who have not smoked at least 100 cigarettes in their lifetime have not become established smokers. These individuals, however, could eventually progress to current smoking. To capture those who have used tobacco products but have not become established users, an additional sample of 938 experimental tobacco users (referred to as “experimenters”) was surveyed. For the purposes of this study, experimenters were defined as those who reported (a) having ever used a tobacco product, even once or twice, (b) not meeting historical usage thresholds for any tobacco product to be considered a “regular” user, and (c) use of tobacco “every day” or “some days” at the time of the study.

In addition, “potential quitters” (n=707) were identified among current tobacco users. For the purposes of this study, potential quitters were defined as those who (a) reported having stopped use of tobacco for one day or longer in the past 12 months in an effort to quit tobacco completely,

(b) indicated they wanted to quit using tobacco “somewhat” or “a lot,” (c) rated the likelihood of trying to quit tobacco in the next 30 days as “somewhat” or “very” likely, and (d) rated the likelihood of being successful in quitting tobacco as “somewhat likely” or “very likely” if a quit attempt was made. Individuals who meet these criteria are considered more likely to quit tobacco use ([Sciamanna et al. 2000](#)) and are an important subgroup in which to examine the effects of the proposed modified risk advertising for Camel Snus.

Procedures

The study was conducted October 20-30, 2014. Respondents were screened for demographics and use of tobacco products (for the screener, see [Protocol Identifier: RO-BR-2014-02 Camel Snus Modified Risk Messaging: Comprehension and Perceptions among Tobacco Users and Non-Users](#)). Qualified respondents were shown the proposed Camel Snus modified risk advertisement that included proposed modified risk messaging. The advertisement consisted of three separate color images that appeared one above the other on the same screen. The bottom fifth of each image included one of four government-mandated warning label statements, randomly rotated for study respondents (for the advertisements viewed by respondents, see [Protocol Identifier: RO-BR-2014-02 Camel Snus Modified Risk Messaging: Comprehension and Perceptions among Tobacco Users and Non-Users](#)).

The proposed modified risk advertising included the following statements (verbatim):

- Smokers who switch completely from cigarettes to Camel Snus can significantly reduce their risk of lung cancer, oral cancer, respiratory disease, and heart disease.
- Smokers who use Camel Snus **instead of** cigarettes can significantly reduce their health risks from smoking.
- No smoke = less risk.
- Scientific studies have shown that Camel Snus contains fewer carcinogens than cigarette smoke.
- No smoke means less risk for you and those around you.
- No tobacco product is safe.
- 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 professional.
- But if you’re not going to quit using tobacco products, you should think about switching to Camel Snus.

Following exposure to the advertisement, respondents were asked questions to assess their comprehension and perceptions of the absolute health risks of Camel Snus, as well as health risks relative to cigarette smoking, cessation aids, and quitting all tobacco use (for the survey, see

[Protocol Identifier: RO-BR-2014-02 Camel Snus Modified Risk Messaging: Comprehension and Perceptions among Tobacco Users and Non-Users](#)). Respondents could view the advertisement and refer to it at any time during the study. The survey questions appeared on the same screen directly below the advertisement, allowing respondents to scroll between the questions and the advertisement as desired. Questions posed to respondents were adapted from published studies that addressed health risk beliefs and risk perceptions of different types of tobacco products (*e.g.*, [Haddock et al. 2004](#); [O’Connor et al. 2005a](#); [Peiper et al. 2010](#)). At the end of the study, a health literacy test (*i.e.*, Newest Vital Sign, NVS) ([Weiss et al. 2005](#)) was completed by all respondents. This test assesses literacy based on respondents' ability to interpret an FDA food label.

Analysis

For the sample as a whole, and for various subgroups, responses to questions addressing the major communications objectives were summarized descriptively by means and 95% confidence intervals (for numerical ratings) or percentages and 95% confidence intervals (for categorical variables). No tests of statistical significance were conducted. For questions about comparative risks of Camel Snus and cigarettes, the proportion of respondents indicating that Camel Snus had at least some risk was computed by combining those who stated that Camel Snus has the same risk as smoking and those who stated that Camel Snus has less risk than smoking but still has some risk. All data were averaged across the sub-samples that each saw one of four randomly-rotated government-mandated smokeless tobacco warning label statements.

6.2.4.2 Study Results

The results of the “Camel SNUS Modified Risk Messaging: Comprehension and Perceptions among Tobacco Users and Non-Users – First Execution of Consumer Testing” study are summarized below. The results are presented for the full sample overall, as well as the particular subgroups for which a specific modified risk message is most relevant (*e.g.*, messaging about quitting tobacco use for current tobacco users, messaging about the health risks of Camel Snus relative to quitting all tobacco use for current tobacco users and potential quitters). In addition, results for certain populations, including minorities and those with limited health literacy, are reported where there are material differences.

The final study report for this study is submitted with this Application and includes the complete tabulation of study results and findings for each of the subgroups of interest (*i.e.*, current tobacco users, former tobacco users, never tobacco users, experimenters, potential quitters, those with limited health literacy, minorities, young adults ages 18-24, and white males) ([Camel SNUS Modified Risk Messaging: Comprehension and Perceptions among Tobacco Users and Non-Users – First Execution of Consumer Testing – Amended Final Report](#)). All results for each subgroup are not repeated in this summary; however, ranges across groups, and particular subgroup results are discussed when particularly relevant or where there are material differences.

6.2.4.2.1 Demographics

Among the 8,404 respondents, 30% (n=2,497) were current tobacco users, 29% (n=2,477) were former tobacco users, 30% (n=2,492) were never tobacco users, and 11% (n=938) were experimenters. Among the current tobacco users, 74% were current cigarette smokers¹ (53% every day; 21% some days), 5% were current snus users, and 12% used other forms of smokeless tobacco. A total of 8% were current users of more than one tobacco product. Respondents were 18 and older, including 23% aged 18-30, 34% aged 31-50, and 43% aged 51 and older. A slight majority (52%) was female; 42% had a high school education, 29% completed some college, and 29% had a bachelor's or advanced degree. The majority of the sample was non-Hispanic Caucasian (66%), 15% were of Hispanic, Latino, or Spanish origin, 12% were non-Hispanic African American, and 7% non-Hispanic Asian or other race. In terms of geographic distribution, 37% were from the South, 23% from the West, 21% from the Midwest, and 18% from the Northeast. The weighted demographic profile of the full sample was comparable to the U.S. population overall (for the demographic profile of the sample by tobacco user group, see [Table 2](#) [unweighted data] and [Table 6](#) [weighted data] in Camel SNUS Modified Risk Messaging: Comprehension and Perceptions among Tobacco Users and Non-Users – First Execution of Consumer Testing – Amended Final Report). A total of 34% of the overall sample was assessed to have limited health literacy, based on the NVS test².

6.2.4.2.2 Respondents' beliefs about the health risks of Camel Snus relative to cigarette smoking, and Camel Snus absolute risks

The FDA MRTPA Draft Guidance indicates that a critical issue to address is consumers' beliefs about the health risks of the MRTP relative to cigarette smoking. Ideally, consumers should understand that the MRTP (Camel Snus) carries lower risk than cigarette smoking for certain diseases, but they should not view the MRTP (Camel Snus) as being completely safe or free of risk.

Respondents' understanding of the risks of Camel Snus relative to cigarette smoking was evaluated in two ways: through comparison of quantitative ratings of risk for each product; and by asking respondents to directly characterize qualitatively the risk of Camel Snus relative to smoking.

¹ Respondents were considered cigarette smokers if they smoked manufactured cigarettes. Only 0.5% (n=42) of respondents indicated smoking roll-your-own cigarettes; these were counted as tobacco users but not cigarette smokers.

² Consistent with findings from other studies ([IOM 2004](#); [Kutner et al. 2006](#); [Rudd 2007](#)), there were substantial variations in assessed health literacy by ethnicity in this study, with African American (52%) and Hispanic (43%) respondents more likely to be assessed as having limited health literacy than Caucasian (29%), Asian (37%), or other respondents (35%). Overall, 44% of minority (non-Caucasian) respondents scored as having limited health literacy. This likely affects comparisons of comprehension by ethnicity.

Quantitative ratings of risk

As one way to capture perceptions of risk, respondents were asked to rate (on a 7-point scale ranging from “no risk” to “substantial risk”) the impact of Camel Snus and cigarette smoking on the risk of developing the four diseases specifically mentioned in the proposed advertisement (*i.e.*, lung cancer, respiratory disease, heart disease, and oral cancer) (Questions 2a-2d on the survey; Protocol Identifier: RO-BR-2014-02 Camel Snus Modified Risk Messaging: Comprehension and Perceptions among Tobacco Users and Non-Users).

Table 6.2.4-1 below summarizes respondents’ beliefs about the health risks associated with Camel Snus and cigarette smoking. Overall, mean risk ratings for Camel Snus for the four diseases specifically mentioned in the advertisement were always lower than those for cigarette smoking, demonstrating that respondents correctly understood the proposed advertising message that Camel Snus presents less risk than cigarette smoking. Notably, the rated difference in risk was highest for respiratory conditions (lung cancer and respiratory disease) and lowest for oral cancer.

At the same time, respondents also understood that Camel Snus nevertheless carried some risk, as is evident from the risk ratings they assigned to Camel Snus on the 1 to 7 scale (Table 6.2.4-1 below). Mean risk ratings for Camel Snus ranged from 4.5 for respiratory disease to 5.6 for oral cancer. Importantly, all Camel Snus risk ratings fell above the midpoint of the 1-7 scale. For comparison, risk ratings for cigarette smoking ranged from 6.0 to 6.5. Therefore, respondents also understood that Camel Snus does pose *at least some risk* for each disease, and that risk is not zero (*i.e.*, no risk at all).

Table 6.2.4-1: Respondents’ (n=8,404) Beliefs about the Health Risks of Camel Snus, Cigarette Smoking, and Smokeless Tobacco

	Camel Snus	Cigarette Smoking	Smokeless Tobacco (other than Camel Snus)
Risk of developing lung cancer *	4.6** (4.55-4.65)	6.5 (6.47-6.53)	5.0 (4.95-5.05)
Risk of developing respiratory disease	4.5 (4.45-4.55)	6.4 (6.37-6.43)	5.0 (4.95-5.05)
Risk of developing heart disease	5.1 (5.05-5.15)	6.3 (6.27-6.33)	5.5 (5.46-5.54)
Risk of developing oral cancer	5.6 (5.56-5.64)	6.0 (5.96-6.04)	6.0 (5.96-6.04)

* Rated on a 7-point scale ranging from 1 (“no risk”) to 7 (“substantial risk”)

** Mean risk rating (95% confidence interval in parentheses)

Indeed, the numerical ratings give some insight into the degree of risk reduction that respondents assumed for Camel Snus compared to smoking. The mean ratings for cigarette smoking are quite high, near the top limit of the scale (designated as "substantial risk"). The

estimates for Camel Snus were lower, but very modestly so³. Even for lung cancer and respiratory disease, respondents on average attributed very substantial risks to use of Camel Snus.

Subgroups of interest

Consistent with the results for the full sample, across each of the subgroups (including limited health literacy and minority respondents) the mean risk ratings for Camel Snus for the four diseases were always lower than those for cigarette smoking ([Appendix B, Table 4](#) and [Table 5](#) in Camel SNUS Modified Risk Messaging: Comprehension and Perceptions among Tobacco Users and Non-Users – First Execution of Consumer Testing – Amended Final Report). Thus, all subgroups understood that Camel Snus poses less risk than cigarette smoking.

The mean risk ratings for all subgroups also indicated understanding that Camel Snus does carry some risk of each disease. Even the lowest mean risk rating assigned to any one disease (respiratory disease) reflected an expectation of significant risk across all subgroups (*e.g.*, current tobacco users [3.6; 95% confidence interval = 3.51-3.69], former tobacco users [4.3; 4.22-4.38], never tobacco users [4.8; 4.73-4.87], experimenters [4.2; 4.03-4.37], and young adults ages 18-24 [4.7; 4.47-4.93]). The perceived risk rating was highest for oral cancer across all subgroups (*e.g.*, current tobacco users [5.3; 5.22-5.38], former tobacco users [5.8; 5.74-5.86], never tobacco users [5.6; 5.53-5.67], experimenters [5.1; 4.93-5.27], and young adults ages 18-24 [5.5; 5.30-5.70] (for detailed results for the subgroups, see [Appendix B, Table 4](#) in Camel SNUS Modified Risk Messaging: Comprehension and Perceptions among Tobacco Users and Non-Users – First Execution of Consumer Testing – Amended Final Report).

Qualitative characterization of risk

In another risk perception question, respondents were asked specifically to characterize the level of risk of using Camel Snus as (a) reduced relative to smoking, (b) similar to that of smoking, (c) having no risk at all, or (d) don't know/not sure response option. These judgments were made separately with respect to lung cancer, respiratory disease, heart disease, and oral cancer (Question 1b on the survey).

[Table 6.2.4-2](#) below summarizes respondents' understanding of the risk reduction of Camel Snus compared to continued smoking. Respondents were very consistent in their responses across the four different disease risks specifically mentioned in the proposed advertisement.

³ It is possible to calculate crude estimates of the relative reduction in risk from the 1-7 risk ratings made by respondents. The ratings were scaled such that 1 = "no risk." Subtracting 1 from the ratings thus sets 0 equal to "no risk," allowing crude computations of risk reduction implied by the ratings, and expressing the risk attributed to Camel Snus as a percentage of that attributed to smoking. On this basis, the respondents' ratings of Camel Snus versus smoking imply a 35% risk reduction for lung cancer and respiratory disease, a 23% reduction for risk of heart disease, and an 8% risk reduction for oral cancer. These implied risk reductions are much more modest than those derived from expert consensus ([Levy et al. 2004](#); [Nutt et al. 2014](#)), which imply roughly 90% risk reduction.

About two-thirds indicated that compared to smoking, Camel Snus has less risk of lung cancer (67%), respiratory disease (66%), and heart disease (64%); the percentage was somewhat lower for oral cancer (57%). Across all four diseases, 9-12% of respondents indicated they did not know or were not sure what the risk of Camel Snus was relative to cigarette smoking.

The basic risk reduction message was not understood, or not believed, by some respondents, such that 15% reported that Camel Snus poses the same risk of lung cancer and respiratory disease, respectively, as cigarette smoking; 19% believed that Camel Snus poses the same risk of heart disease; and 32% believed that Camel Snus posed the same risk of oral cancer as cigarette smoking.

Approximately 10% of respondents did not know or were not sure what the risk of Camel Snus was, whether on an absolute or relative basis.

Consistent with the quantitative ratings, few respondents believed that Camel Snus had no risk at all. This risk characterization was endorsed by less than 10% of respondents, across diseases. This figure was lowest for oral cancer, at 3%. Similarly, 82%-89% indicated that Camel Snus carries at least some risk for each disease. This suggests that respondents understood that Camel Snus is not risk-free and still poses some risk.

Table 6.2.4-2: Respondents’ (n=8,404) Understanding of the Health Risks of Camel Snus Relative to Continuing to Smoke

	Same risk as continuing to smoke	Less risk than continuing to smoke, but some risk	Net “some risk”	No risk at all	Don’t know / Not sure
Lung cancer risk	15% (14.1%-15.9%)*	67% (65.8%-68.2%)	82% (81.0%-83.0%)	9% (8.3%-9.7%)	10% (9.2%-10.8%)
Respiratory disease risk	15% (14.0%-16.0%)	66% (64.8%-67.2%)	82% (81.0%-83.0%)	8% (7.3%-8.7%)	10% (9.2%-10.8%)
Heart disease risk	19% (18.0%-20.0%)	64% (62.8%-65.2%)	83% (82.0%-84.0%)	5% (4.5%-5.5%)	12% (11.2%-12.8%)
Oral cancer risk	32% (30.8%-33.2%)	57% (55.7%-58.3%)	89% (88.2%-89.8%)	3% (2.6%-3.4%)	9% (8.2%-9.8%)

*95% confidence interval

Subgroups of interest

Among current tobacco users – a subgroup for whom the modified risk advertising is particularly relevant – at least 78% stated that Camel Snus is associated with some risk of each disease. For oral cancer, only 3% (2.2%-3.8%) of current tobacco users stated that Camel Snus was associated with no risk, whereas this figure was 14% (12.4%-15.6%) for lung cancer and respiratory disease, respectively (for detailed results across subgroups, see [Appendix A, Table 3](#) in Camel SNUS Modified Risk Messaging: Comprehension and Perceptions among Tobacco Users and Non-Users – First Execution of Consumer Testing – Amended Final Report). Similarly, among potential

quitters – another subgroup for whom this message is highly relevant – at least 79% stated that Camel Snus is associated with some risk of each disease. Again, only 3% (1.7%-4.3%) reported no risk for oral cancer, while 15% (11.9%-18.1%) reported no risk for respiratory disease, and 14% (11.1%-16.9%) reported no risk for lung cancer.

As expected, those with limited health literacy demonstrated lower overall comprehension of or belief in the risk reduction messaging, relative to all other respondents. For each of the four diseases, slightly less than 50% of those with limited health literacy correctly indicated Camel Snus poses less risk than smoking, while 26% to 38% indicated equal risk for Camel Snus and smoking. However, consistent with the responses of all other respondents, less than 10% of limited health literacy respondents incorrectly indicated that the advertisement conveyed no risk at all with Camel Snus for each of the diseases ([Appendix A, Table 3](#) in Camel SNUS Modified Risk Messaging: Comprehension and Perceptions among Tobacco Users and Non-Users – First Execution of Consumer Testing – Amended Final Report), suggesting that this misperception was not prevalent even among those who may have had trouble understanding the messaging.

Among minority (*i.e.*, non-Caucasian) respondents, at least 80% stated that Camel Snus is associated with some risk of each disease. Only 3% (2.2%-3.8%) (for oral cancer), 5% (4.0%-6.0%) (for heart disease), and 8% (6.8%-9.2%) (for lung cancer and respiratory disease, respectively) incorrectly indicated no risk at all, again suggesting understanding of this aspect of the message. In no subgroup examined did the percentage of respondents believing Camel Snus posed no risk at all exceed 15% (this was the highest percentage, among potential quitters, for risk of respiratory disease).

6.2.4.2.3 Perceptions of risk across the diseases mentioned in the proposed advertisement

The proposed advertisement mentioned reduced risk of lung cancer, respiratory disease, heart disease, and oral cancer. Although the proposed advertisement did not explicitly distinguish the relative risk for these four conditions, respondents appeared to do so in their ratings of risk. Respondents consistently rated the risk of oral cancer higher than that of the respiratory conditions – in quantitative ratings using the 1 to 7 scale ([Table 6.2.4-1](#) above), the risk of oral cancer was rated at 5.6, whereas the risk of lung cancer was rated 4.6 and respiratory disease was rated 4.5. The risk of heart disease was intermediate at 5.1. Similarly, in qualitative ratings ([Table 6.2.4-2](#) above), 32% thought the risk of Camel Snus for oral cancer was the same as that associated with continuing to smoke; in contrast, this figure was 15% for lung cancer and respiratory disease, and 19% for heart disease. Conversely, whereas 8-9% believed that Camel Snus carried no risk at all for respiratory disease and lung cancer, only 3% saw no risk for oral cancer and 5% saw no risk for heart disease.

This pattern of beliefs about risk corresponds to that seen in recent qualitative research on the public's perceptions of snus ([Choi et al. 2012](#)), where respondents inferred oral cancer risk from the fact that oral tobacco products come into direct contact with the mouth. That the results in the present comprehension and perceptions study mirrored those results indicates that respondents' stated risk perceptions were partly influenced by their pre-existing beliefs or

assumptions, even though respondents were asked to respond according to the information presented in the proposed advertisement.

Subgroups of interest

Each of the different subgroups rated the risk of oral cancer higher than that of the respiratory conditions in the quantitative assessment of risk ([Appendix B, Table 4](#) in Camel SNUS Modified Risk Messaging: Comprehension and Perceptions among Tobacco Users and Non-Users – First Execution of Consumer Testing – Amended Final Report). The lowest mean risk rating was always assigned to respiratory disease across all subgroups (mean ratings ranged from 3.6 to 4.8), but such ratings still reflect a perception of some risk posed by Camel Snus.

In the qualitative assessment of risk ([Appendix A, Table 3](#) in Camel SNUS Modified Risk Messaging: Comprehension and Perceptions among Tobacco Users and Non-Users – First Execution of Consumer Testing – Amended Final Report), the percentage of respondents in each subgroup indicating that Camel Snus posed no risk at all was always highest for lung cancer or respiratory disease risk, and lowest for oral cancer risk, consistent with the trends in the sample as a whole, and with trends seen in the published literature on the public's risk perceptions about smokeless tobacco and snus compared to cigarettes ([Choi et al. 2012](#); [Pepper et al. 2015](#); [Wray et al. 2012](#)). Across all subgroups, at least 75% indicated that Camel Snus is associated with some risk of each of the four diseases (*e.g.*, 78% for current tobacco users, 80% for minority respondents, and 85% for former tobacco users), and the percentage of respondents believing that Camel Snus posed at least some risk was always highest for oral cancer (*e.g.*, 91% for current tobacco users, 85% for minority respondents, and 93% for former tobacco users).

6.2.4.2.4 Respondents' Understanding of Relative Risks for Diseases Not Mentioned in the Proposed Advertisement

It was conceivable that respondents might generalize the information provided in the proposed modified risk advertisement to apply to diseases not explicitly mentioned. To assess for such generalization, a question was posed regarding the risk reduction potential of Camel Snus for other diseases *not mentioned in the advertisement* (Question 2g on the survey).

Across all respondents, 15% (14.1%-15.9%) believed that “Camel Snus reduces the risk of other smoking-related diseases that are not discussed in the ad” (yes/no/don't know response options); 32% (30.8%-33.2%) indicated 'no', but most (53%; 51.7%-54.3%) were understandably unsure. Although some generalization is likely reasonable, the data suggest that the messaging did not lead respondents to make sweeping generalizations or draw strong conclusions about diseases not explicitly mentioned in the advertisement ([Table 9](#) in Camel SNUS Modified Risk Messaging: Comprehension and Perceptions among Tobacco Users and Non-Users – First Execution of Consumer Testing – Amended Final Report).

Subgroups of interest

The results for the diseases “not mentioned in the advertisement” question for the different subgroups were similar to those for all respondents ([Appendix B, Table 7](#) in Camel SNUS Modified Risk Messaging: Comprehension and Perceptions among Tobacco Users and Non-Users – First Execution of Consumer Testing – Amended Final Report). Those who reported that Camel Snus reduced the risk of other diseases not mentioned in the advertisement ranged from a low of 13% for young adults ages 18-24 to a high of 24% for experimenters. In addition, 28-38% in each subgroup indicated ‘no’, and 45-58% were unsure. Of interest, among all of the different subgroups, those most likely to say that Camel Snus did not reduce the risk of diseases not mentioned in the advertisement included young adults (38%; 32.4%-43.6%), those with limited health literacy (37%; 34.8%-39.2%), and never tobacco users (36%; 34.1%-37.9%).

6.2.4.2.5 Respondents’ Beliefs about the Risk of Developing Generally Poorer Health

Respondents were also asked to rate the impact of Camel Snus, cigarette smoking, and smokeless tobacco use (other than Camel Snus) on risk of “developing generally poorer health”, using the same scale used to rate Camel Snus and cigarette smoking (a 7-point scale ranging from “no risk” to “substantial risk”; Question 2e on the survey). The proposed advertisement did not include any specific reference to overall health but mentioned four serious diseases (lung cancer, oral cancer, respiratory disease, and heart disease) that might be taken as relevant to overall health status.

[Table 6.2.4-3](#) below shows respondents’ mean risk ratings for the risk of developing poorer health for Camel Snus and cigarette smoking. The ratings show that the risk for Camel Snus (5.5) is rated as lower than that of cigarette smoking (6.4). The risk rating assigned to Camel Snus for overall health was higher than that assigned to it for risk of lung cancer, respiratory disease, and heart disease, and similar (though slightly lower) than that assigned for oral cancer ([Table 6.2.4-1](#) above). The ratings suggest that respondents believed that Camel Snus carries considerable risk to overall health, though not as high a risk as smoking does.

Table 6.2.4-3: Respondents’ (n=8,404) Beliefs about the Risk of Developing Poorer Health for Camel Snus, Cigarette Smoking, and Smokeless Tobacco

	Camel Snus	Cigarette Smoking	Smokeless Tobacco (other than Camel Snus)
Risk of developing generally poorer health	5.5 (5.46-5.54)	6.4 (6.37-6.43)	5.9 (5.86-5.94)

* Rated on a 7-point scale ranging from 1 (“no risk”) to 7 (“substantial risk”)

** Mean risk rating (95% confidence interval in parentheses)

Subgroups of interest

The results across the subgroups for ratings of risk of developing generally poorer health were consistent with those for the full sample – for each subgroup, the mean risk ratings for Camel Snus (range = 5.0-5.7) were always lower than those for cigarette smoking (range = 6.0-6.6) ([Appendix B, Table 4](#) and [Table 5](#) in Camel SNUS Modified Risk Messaging: Comprehension and

Perceptions among Tobacco Users and Non-Users – First Execution of Consumer Testing – Amended Final Report). In addition, across each of the different subgroups, the risk rating assigned to Camel Snus for overall health was higher than that assigned to it for risk of lung cancer, respiratory disease, and heart disease, and similar (though sometimes slightly lower) than that assigned for oral cancer.

6.2.4.2.6 Respondents’ Beliefs about the Health Risks of Camel Snus Relative to Smokeless Tobacco

In addition to assessing comprehension of how the risk of Camel Snus compares with cigarette smoking, FDA’s MRTPA Draft Guidance recommends that applicants also assess perceptions of risk for the MRTP compared to other tobacco products in the same class. Accordingly, respondents were also asked to rate the impact of smokeless tobacco use (other than Camel Snus) on the risk of developing the four diseases specifically mentioned in the proposed advertisement (*i.e.*, lung cancer, oral cancer, respiratory disease, and heart disease), using the same scale used to rate Camel Snus and cigarette smoking (a 7-point scale ranging from “no risk” to “substantial risk”; Questions 2a-2d on the survey).

[Table 6.2.4-1](#) above summarizes respondents’ ratings of the health risks associated with Camel Snus and smokeless tobacco use. The ratings show that the risks of other smokeless tobacco products are rated as higher than that of Camel Snus for each of the four diseases, with the difference between Camel Snus and other smokeless tobacco products being consistently smaller than that between Camel Snus and cigarette smoking. Mean risk ratings for cigarette smoking were always the highest, except in the case of “risk of developing oral cancer” for which cigarette smoking and other smokeless tobacco products were considered equally risky (mean = 6.0). These results suggest good comprehension of the modified risk advertising – respondents reported that other smokeless tobacco products pose more risk of the four diseases than Camel Snus. In a similar vein, as seen in [Table 6.2.4-3](#), the risk of other smokeless tobacco on “generally poorer health” was rated higher than the risk of Camel Snus (5.9 vs. 5.5), but lower than the risk of cigarette smoking (6.4). This suggests that respondents did not generalize the modified risk advertising to apply to all smokeless tobacco products.

Subgroups of interest

Consistent with the results for the full sample, across each of the subgroups (including those with limited health literacy and minority respondents) the mean risk ratings for other smokeless tobacco for the four diseases were always higher than those for Camel Snus ([Appendix B, Table 4](#) and [Table 6](#) in Camel SNUS Modified Risk Messaging: Comprehension and Perceptions among Tobacco Users and Non-Users – First Execution of Consumer Testing – Amended Final Report). This suggests all subgroups perceived that other smokeless tobacco poses more risk than Camel Snus, and that the modified risk advertising was not generalized to all smokeless tobacco.

6.2.4.2.7 Respondents' Beliefs about the Health Risks of Camel Snus Relative to Smoking Cessation Aids

Because FDA's MRTP Draft Guidance recommends that perceived risk be evaluated in comparison to therapeutic nicotine replacement products, respondents were asked about the health risks of Camel Snus compared to nicotine replacement products (Question 5a on the survey). There was no mention of cessation products or other nicotine products in the proposed advertisement. Across all respondents, 68% (66.8%-69.2%) endorsed the statement that "Camel Snus is NOT a safer alternative than products that are used to quit tobacco such as gum, patches, and lozenges" (true/false/don't know response options). The remaining respondents considered the statement untrue (14%; 13.1%-14.9) or, more commonly, were unsure of the correct response (18%; 17.0%-19.0%), as this issue was not directly addressed in the proposed advertisement. A possible explanation for an incorrect response (*i.e.*, cessation products are not safer than Camel Snus) could be that respondents, like many in the population, had pre-existing misperceptions about the safety of nicotine replacement therapies (NRTs). Studies have demonstrated widespread misperceptions about the safety and addictive potential of NRT overall and relative to cigarettes (Ferguson *et al.* 2011; Silla *et al.* 2014; Shiffman *et al.* 2008).

Subgroups of interest

Among potential quitters, for whom NRT would be an appropriate consideration, 69% (65.0%-73.0%) endorsed the statement (*i.e.*, Camel Snus is not a safer alternative to products used to quit tobacco), while 20% (16.4%-23.6%) did not, and 11% (8.3%-13.7%) were unsure whether Camel Snus is a safer alternative than NRT. Those with limited health literacy were the subgroup most likely to believe the statement was false (20%; 18.2%-21.8%) and to say they did not know the answer (25%; 23.0%-27.0%), and were the least likely to endorse the statement (55%; 52.8%-57.2%). Across the different subgroups, former tobacco users, who may be more familiar with NRT, were most likely to endorse the statement (75%; 73.1%-76.9%) (for detailed results across the different subgroups, see Table 9 and Appendix B, Table 8 in Camel SNUS Modified Risk Messaging: Comprehension and Perceptions among Tobacco Users and Non-Users – First Execution of Consumer Testing – Amended Final Report).

6.2.4.2.8 Respondents' Beliefs about the Health Risks of Camel Snus Relative to Quitting All Tobacco Use

In accordance with the Draft Guidance for MRTPAs, respondents were also asked about the safety of Camel Snus relative to stopping use of all tobacco products (Question 5b on the survey). Although the proposed advertisement did not explicitly state that cessation of all tobacco use is safer than Camel Snus, it did state "*If you're a smoker concerned about the health risks from smoking, the best choice is to quit*" and "*No tobacco product is safe.*" (Italics added.) In addition, 25% of the full sample viewed a proposed advertisement with the government-mandated warning label statement "WARNING: This product is not a safe alternative to cigarettes."

Across all respondents, 71% (69.8%-72.2%) correctly responded that “Camel Snus is NOT a safer alternative than quitting tobacco entirely”; 17% (16.0%-18.0%) answered incorrectly, and 12% (11.1%-12.9%) were unsure of the correct response (true/false/don’t know response options).

Subgroups of interest

Among current tobacco users and potential quitters – two subgroups for whom this particular message is most relevant – seven of ten in each group (70% [67.9%-72.1%] and 70% [66.0%-74.0%], respectively) gave the correct response (true), almost one-quarter in each of these groups (22% [20.1%-23.9%] and 24% [20.3%-27.7%]) answered incorrectly, and 8% (6.7%-9.3%) and 6% (3.8%-8.2%) were unsure of whether Camel Snus is a safer alternative to quitting all tobacco use.

Comprehension of this message (*i.e.*, quitting all tobacco use is safer than Camel Snus) is also important for former tobacco users who might be tempted to resume tobacco use with Camel Snus. In this group, 78% (76.2%-79.8%) answered correctly, 15% (13.5%-16.5%) answered incorrectly, and 8% (6.8%-9.2%) were unsure of the correct response. Those with limited health literacy had the lowest proportion of correct responses (58%; 55.8%-60.2%) and the highest proportion of “don’t know/unsure” responses (21%; 19.1%-22.9%) (Table 9 and [Appendix B, Table 9](#) in Camel SNUS Modified Risk Messaging: Comprehension and Perceptions among Tobacco Users and Non-Users – First Execution of Consumer Testing – Amended Final Report).

6.2.4.2.9 Respondents’ Beliefs about the Addictiveness of Camel Snus

6.2.4.2.9.1 Respondents’ Understanding of the Proposed Advertising – Camel Snus is Addictive

Respondents’ perceptions about the addictiveness of Camel Snus were assessed in two ways: a dichotomous qualitative question, and a quantitative rating question.

Qualitative assessment

Respondents’ understanding that Camel Snus is addictive was assessed in a question that simply asked “Is Camel Snus, which contains nicotine, addictive?” (yes/no/don’t know response options; Question 1a on the survey). Among all respondents, 82% (81.0%-83.0%) correctly stated that Camel Snus is addictive. Most of the remainder (13%; 12.1%-13.9%) were unsure of the correct response, while 5% (4.4%-5.6%) indicated it is not addictive.

Subgroups of interest

Across the subgroups, those with limited health literacy had the lowest proportion of correct responses for this particular question (65%; 62.8%-67.2%) and the highest proportion of do not know responses (24%; 22.1%-25.9%) as well as incorrect responses (11%; 9.6%-12.4%). Given the prominent and explicit statements in the proposed advertisement regarding the addictive potential of Camel Snus that were virtually identical to the question itself, as well as the government-mandated addiction warning label statement displayed to one-quarter of

participants, it is unclear why some respondents answered incorrectly or were unsure of the correct response.

Over 80% of young adults ages 18-24 answered correctly (83%; 77.2%-88.8%), 11% (7.3%-14.7%) were unsure of the correct response, and a small proportion (6%; 3.4%-8.6%) answered incorrectly. Understanding that Camel Snus is addictive is also important for experimenters, who may ultimately progress to regular tobacco use – 76% (72.1%-79.9%) answered correctly, 16% (12.5%-19.5%) were unsure of the correct response, and 8% (5.5%-10.5%) answered incorrectly (for detailed results across the different subgroups, see [Table 8](#) and [Appendix A, Table 1](#) in Camel SNUS Modified Risk Messaging: Comprehension and Perceptions among Tobacco Users and Non-Users – First Execution of Consumer Testing – Amended Final Report).

Quantitative assessment

An additional assessment of the perceived addictiveness of Camel Snus was obtained by asking respondents to quantitatively rate the addictive potential of Camel Snus on a 1-7 scale ranging from “not at all addictive” to “extremely addictive” (Question 2f on the survey).

As shown in [Table 6.2.4-4](#), respondents rated the addictiveness of Camel Snus at 5.9 on the 7-point scale, indicating a substantial degree of perceived addictiveness. Indeed, this risk rating was higher than the ratings assigned by respondents for perceived risk of the four diseases for which reduced risk was claimed ([Table 6.2.4-1](#) above).

Table 6.2.4-4: Respondents’ (n=8,404) Beliefs about the Addictiveness of Camel Snus, Cigarette Smoking, and Smokeless Tobacco

	Camel Snus	Cigarette Smoking	Smokeless Tobacco (other than Camel Snus)
How addictive *	5.9** (5.86-5.94)	6.5 (6.47-6.53)	6.2 (6.17-6.23)

* Rated on a 7-point scale ranging from 1 (“not at all addictive”) to 7 (“extremely addictive”)

** Mean risk rating (95% confidence interval in parentheses)

Subgroups of interest

The ratings of addictiveness of Camel Snus across subgroups were consistent with those for the full sample – each subgroup, respectively, rated the addictive potential of Camel Snus as high – 5.9 (5.72-6.08) for young adults ages 18-24; 5.9 (5.84-5.96) for never tobacco users; 5.4 (5.24-5.56) for experimenters; and 5.4 (5.32-5.48) for those with limited health literacy (for detailed results across the different subgroups, see [Table 9](#) and [Appendix B, Table 4](#) in Camel SNUS Modified Risk Messaging: Comprehension and Perceptions among Tobacco Users and Non-Users – First Execution of Consumer Testing – Amended Final Report).

6.2.4.2.9.2 Respondents' Beliefs about the Addictiveness of Camel Snus Relative to Cigarette Smoking and Other Smokeless Tobacco Products

Respondents were also asked to give quantitative ratings of the addictive potential of cigarette smoking and other smokeless tobacco use, which allowed for assessment of respondents' perceptions of relative addictiveness. The ratings were made on a 1-7 scale ranging from "not at all addictive" to "extremely addictive" (Question 2f on the survey). The proposed advertisement seen by respondents explicitly stated that Camel Snus is addictive, but did not provide comparative information on addiction relative to cigarette smoking or other smokeless tobacco.

As shown in [Table 6.2.4-4](#) above, respondents rated the addictiveness of Camel Snus as lower than that of other smokeless tobacco products and cigarette smoking, respectively. The perception of lower addictive potential was modest, amounting to 0.6 points on the 7-point scale when compared to smoking, and 0.3 points on that scale when compared to other smokeless tobacco products.

Subgroups of interest

As in the full sample, the perceived addictiveness of Camel Snus was always rated as lower than that of cigarette smoking and other smokeless tobacco across each of the different subgroups. The ratings suggest that respondents believed that Camel Snus is clearly addictive, though slightly less addictive than either cigarette smoking or other smokeless tobacco use ([Appendix B, Table 4, Table 5, and Table 6](#) in *Camel SNUS Modified Risk Messaging: Comprehension and Perceptions among Tobacco Users and Non-Users – First Execution of Consumer Testing – Amended Final Report*).

6.2.4.2.10 Additional Messages in the Interest of Public Health

6.2.4.2.10.1 Respondents' Understanding of the Proposed Advertising – Switching Completely to Camel Snus to Reduce Health Risks

The reduction of risk associated with switching from cigarette smoking to Camel Snus is best achieved by switching completely from smoking to Camel Snus. To communicate this concept, the proposed modified risk advertisement states "*Smokers who switch completely from cigarettes to Camel Snus can significantly reduce their risk of lung cancer, oral cancer, respiratory disease, and heart disease.*" In addition, other statements in the proposed advertisement stress "switching" to Camel Snus: "*Switch completely from cigarettes to Camel Snus*"; "*I'm a smoker. Why should I switch?*"; "*But if you're not going to quit using tobacco products, you should think about switching to Camel Snus.*" (Emphasis added throughout.) Therefore, a question was included to assess whether respondents understood that smokers' health risks are reduced only if they quit smoking completely and use Camel Snus *instead of* cigarettes. Respondents were asked what action was needed in order for smokers to receive a health benefit from using Camel Snus, and three response options were provided: 1) stop smoking completely and use Camel Snus instead; 2) reduce smoking by half and use Camel Snus in addition; and 3) not change smoking behavior and use Camel Snus as well (Question 1a2 on the survey).

Almost three-quarters (72%; 70.8%-73.2%) of all respondents indicated that smokers should “stop smoking completely and use Camel Snus instead” in order to receive a health benefit, while 10% (9.2%-10.8%) indicated that smokers could achieve a health benefit by reducing their smoking by half. Very few respondents indicated that Camel Snus should be used in addition to smoking, with no change in smoking behavior (3%; 2.6%-3.4%). A total of 15% (14.1%-15.9%) were unsure of the correct response to this question.

Subgroups of interest

Comprehension of the message about complete switching is particularly important for current tobacco users and potential quitters, who must understand that completely stopping smoking is required to receive a health benefit when using Camel Snus. Among current tobacco users, 72% (69.9%-74.1%) indicated that smokers should switch completely to Camel Snus; 13% (11.5%-14.5%) indicated that smokers should reduce their smoking; very few indicated that Camel Snus should be used in addition to smoking, with no change in smoking behavior (3%; 2.3%-3.7%); and 12% (10.5%-13.5%) were unsure. Among potential quitters, 72% (68.0%-76.0%) indicated that smokers should switch completely to Camel Snus; 15% (11.9%-18.1%) indicated that smokers should reduce their smoking; very few respondents indicated that Camel Snus should be used in addition to smoking (4%; 2.2%-5.8%); and 9% (6.4%-11.6%) were unsure of the correct response.

Across the other subgroups, only small percentages indicated that Camel Snus should be used in addition to smoking, with no change in smoking behavior (from a low of 2% for former tobacco users and white males, respectively, to a high of 6% for experimenters). Those with limited health literacy were least likely to say that complete switching to Camel Snus was necessary (53%; 50.8%-55.2%) and most likely to say they did not know the answer (26%; 24.0%-28.0%); in this subgroup, 16% (14.4%-17.6%) indicated that smokers should reduce their smoking and use Camel Snus as well, while very few indicated that Camel Snus should be used in addition to smoking, with no change in smoking behavior (5%; 4.0%-6.0%). (for detailed results across the different subgroups, see [Appendix A, Table 2](#) in Camel SNUS Modified Risk Messaging: Comprehension and Perceptions among Tobacco Users and Non-Users – First Execution of Consumer Testing – Amended Final Report).

6.2.4.2.10.2 Respondents’ Understanding of the Proposed Advertising Emphasizing that Quitting Smoking is the Best Choice

For smokers concerned about the health risks of smoking, it is important that they understand that Camel Snus reduces some health risks compared to cigarette smoking, but quitting smoking is the best way to eliminate those risks. Understanding of this message aims to mitigate the possibility that smokers who might otherwise quit might adopt Camel Snus instead of quitting tobacco completely. Accordingly, the proposed advertisement indicates quitting as the best choice: *“If you’re a smoker concerned about the health risks from smoking, the best choice is to quit.”* (Italics added.) To assess understanding of this concept, respondents were asked whether “Quitting is the best choice for a smoker who is concerned about health risks from smoking” (yes/no/don’t know response options; Question 1a on the survey).

A strong majority of all respondents (89%; 88.2%-89.8%) correctly understood this message, with small proportions indicating the wrong answer (6%; 5.4%-6.6%) or being unsure of the correct answer (6%; 5.4%-6.6%).

Subgroups of interest

There was also excellent comprehension of the “best choice is to quit” message among the subgroups for whom this message is most relevant – 91% (89.7%-92.3%) of current tobacco users, 95% (94.0%-96.0%) of former tobacco users, and 93% (90.8%-95.2%) of potential quitters indicated that quitting is the best choice for a smoker concerned about the health risks from smoking. Across the subgroups, those with limited health literacy had the lowest proportion of correct responses for this particular question (79%; 77.1%-80.9%), but still showed good comprehension (for the full results across the subgroups, see [Table 8](#) and [Appendix A, Table 1](#) in Camel SNUS Modified Risk Messaging: Comprehension and Perceptions among Tobacco Users and Non-Users – First Execution of Consumer Testing – Amended Final Report).

6.2.4.2.10.3 Respondents’ Understanding of the Message that Former and Never Users of Tobacco Products Should Not Use Camel Snus

The proposed advertisement indicated that Camel Snus should not be used by non-tobacco users (both never and former users): “*Adults who do not use or who have quit using tobacco products should not start using Camel Snus.*” To ensure respondents understood that Camel Snus should not be used by non-tobacco users, they were asked “Should adults who do not use or who have quit using tobacco products start using Camel Snus?” (yes/no/don’t know response options; Question 1a on the survey).

This message was correctly understood by 84% (83.0%-85.0%) of respondents overall; a small percentage (5%; 4.5%-5.5%) provided the incorrect response (yes); and 11% (10.2%-11.8%) were unsure of the correct response even though this question mirrored the statement in the advertisement.

Subgroups of interest

This message is particularly important for former tobacco users and never tobacco users, who should not start using any tobacco product, including Camel Snus. The message that Camel Snus should not be used by those who don’t use tobacco products was well understood by former tobacco users (90%; 88.7%-91.3%) and never tobacco users (82%; 80.5%-83.5%). In the former and never tobacco user subgroups, those unsure of the correct response were 6% (5.0%-7.0%) and 13% (11.6%-14.4%), respectively. Among those with limited health literacy, 72% (70.0%-74.0%) answered correctly, but 20% (18.2%-21.8%) were unsure of the correct response (for the full results across the subgroups, see [Table 8](#) and [Appendix A, Table 1](#) in Camel SNUS Modified Risk Messaging: Comprehension and Perceptions among Tobacco Users and Non-Users – First Execution of Consumer Testing – Amended Final Report).

6.2.4.3 Conclusions

The “Camel SNUS Modified Risk Messaging: Comprehension and Perceptions among Tobacco Users and Non-Users: First Execution of Consumer Testing” study was conducted in accordance with the FDA’s MRTPA Draft Guidance to evaluate the effects of the proposed modified risk advertising for Camel Snus on current tobacco users’ and non-users’ understanding and perceptions. Overall, the results of this study suggest good comprehension of the proposed modified risk advertising for Camel Snus, and little indication that respondents were misled by the messaging. Across the different questions posed to respondents, although less than perfect comprehension was demonstrated, strong majorities showed understanding of the absolute and relative risks of Camel Snus in the context of the following messaging:

- Camel Snus poses less risk than cigarette smoking for particular diseases (*i.e.*, lung cancer, respiratory disease, heart disease, and oral cancer).
- However, Camel Snus is not completely without risk.
- Camel Snus is not a safer alternative than NRTs that are used to quit tobacco.
- Camel Snus is not a safer alternative than quitting tobacco entirely.
- Camel Snus is addictive.
- Current smokers who switch completely from cigarettes to Camel Snus can significantly reduce their health risks.
- Quitting all tobacco products is the best choice for current tobacco users concerned about health risks.
- Former and never users of tobacco products should not use Camel Snus.

A key message conveyed in the tested proposed advertisement was that Camel Snus reduces the health risks of lung cancer, respiratory disease, heart disease, and oral cancer. This message was understood by a majority of respondents – about two-thirds indicated that Camel Snus carried less risk (but still some risk) for the first three conditions, and average ratings of risk were lower for Camel Snus relative to cigarette smoking. Thus, the advertisement generally conveyed the concept of reduced risk for Camel Snus.

Importantly, respondents understood that Camel Snus was not completely safe and still carried some risk. Less than 10% considered Camel Snus to be without risk for the diseases assessed, and perceived risk ratings consistently averaged above 4 on a 7-point risk scale (where 1 meant no risk), implying considerable risk. Thus, respondents viewing the proposed advertisement did not over-extend the messaging to conclude that Camel Snus was completely safe. This is an important finding, as it supports the idea that smokers may benefit from switching from cigarette

smoking to Camel Snus, but that non-tobacco-users should not adopt use of Camel Snus, as this may subject them to risk.

Similarly, respondents did not over-generalize the stated risk reduction to general health, rating the risk of Camel Snus to "generally poor health" at 5.5 on the 7-point risk scale, where 1 represented no risk. In other words, respondents considered that use of Camel Snus was a considerable risk to health, beyond the specific diseases mentioned. The advertisement did not address the effect of Camel Snus on any other disease, leading 85% to conclude that it either did not reduce the risk of other diseases (32%) or that they did not know its effect on other diseases (53%). Respondents also generally understood that Camel Snus is addictive. Thus, the modified risk messaging in the proposed advertisement led to respondent beliefs that were typically neither overstated nor over-generalized.

Indeed, respondents' assumptions about the expected reduction in risk from switching from cigarette smoking to Camel Snus appeared to be quite modest, likely understating the actual risk reduction, particularly for lung cancer and respiratory diseases. Further, given the explicit statements in the advertisement that Camel Snus reduced the risk of the four diseases listed, it was striking that substantial minorities of respondents stated that Camel Snus carried the *same* risk as continuing to smoke: 32% believed this for oral cancer, and 15-19% for lung cancer, respiratory disease, and heart disease. Also, as suggested by these estimates, respondents made distinctions among the diseases mentioned in the proposed advertisements, even though the advertisement noted risk reduction for each of them without distinguishing among them or providing comparative or quantitative information. This strongly suggests that the respondents formulated their responses not just based on what they read and understood from the advertisement itself, but additionally were influenced by pre-existing beliefs and intuitions. Multiple findings indicate that many Americans believe that smokeless tobacco is as dangerous or more dangerous than smoking (Fong *et al.* 2016; Kaufman *et al.* 2014; Kiviniemi and Kozlowski 2015; Liu *et al.* 2015; O'Connor *et al.* 2005a; Regan *et al.* 2012; Smith *et al.* 2007; Wray *et al.* 2012), and particularly believe that since smokeless tobacco comes in contact with the mouth, but, unlike smoking, is not inhaled, that its effects would be greater on oral cancer than on diseases of the respiratory system (lung cancer and respiratory disease) (Choi *et al.* 2012; Pepper *et al.* 2015).

Thus, the opinions provided by respondents after exposure to the advertisement must be seen in the context of the prevailing public misperception that smokeless tobacco, including snus, is at least as harmful as smoking (Fong *et al.* 2016; Kaufman *et al.* 2014; Kiviniemi and Kozlowski 2015; Liu *et al.* 2015; Regan *et al.* 2012; Wray *et al.* 2012), especially for oral cancer (Choi *et al.* 2012; Pepper *et al.* 2015). Given this prevailing view, and the skepticism with which reduced risk information is received (Borland *et al.* 2012), it is understandable that some respondents continued to believe that Camel Snus was as harmful as smoking. In practice, modified risk messaging may need repetition and endorsement from multiple credible sources to become more persuasive and believable to consumers, so as to change their beliefs and to support changes in tobacco use behavior.

Respondents not only did not overstate the risk reduction attributable to Camel Snus, but they also did not over-generalize it to all other smokeless products. The risk of other smokeless tobacco products was rated higher than that of Camel Snus for each of the four diseases mentioned in the advertisement. Nor did most respondents believe that Camel Snus was as safe as nicotine replacement medications, though this comparison was less well understood than the comparison to cigarette smoking. This is not surprising in light of shared misperceptions about the harms of nicotine even in FDA-approved medications (Borland *et al.* 2011; Ferguson *et al.* 2011; Smith *et al.* 2007), and the widespread belief that nicotine is a primary harmful ingredient in tobacco and NRT products (Bansal *et al.* 2004; Ferguson *et al.* 2011; Mooney *et al.* 2006). Mitigating public misperceptions about Camel Snus may benefit from addressing broader misconceptions about nicotine and its role in smoking-related harms (Borland *et al.* 2011; Borland *et al.* 2012; Ferguson *et al.* 2011; Regan *et al.* 2012).

6.2.4.3.1 Subgroups

Certain messages in the proposed advertisement are of special relevance to particular subgroups. Accordingly, comprehension and perceptions were also evaluated in subgroups of interest. The results showed good comprehension for most of these message-by-subgroup pairings. For example, almost all current tobacco users (91%) understood the message that quitting smoking is the best option for smokers concerned about health risks. This suggests that messages about reduced risk would not deter smokers from quitting, and that using Camel Snus would not be seen as an adequate substitute for quitting. Most current tobacco users (72%) understood that smokers' health risks are reduced only if they stop smoking completely and use Camel Snus instead of cigarettes. Some (13%) assumed, perhaps by reasonable intuition, that using Camel Snus to reduce smoking by half would be enough to receive a health benefit and some reduction in risk. Very few (3%) said that Camel Snus would confer a health benefit if used in addition to current smoking. Thus, respondents generally understood that the benefit of Camel Snus would come from substituting Camel Snus for smoking, and that the optimal course was to stop smoking without the use of Camel Snus.

Further, current tobacco users who were potential quitters had excellent understanding (93%) of the message that quitting is the best choice for smokers, suggesting that the offer of Camel Snus would not lead them to think of Camel Snus as an alternative to quitting, and thus deter them from quitting. Similarly, subgroups that were not current tobacco users – former tobacco users and never users – well understood that non-users should not use Camel Snus (90% and 82%, respectively), suggesting that the messaging would not attract initiation among these non-user groups.

The study also evaluated comprehension and perceptions among individuals with limited health literacy. Studies have consistently demonstrated that limited health literacy is associated with lower comprehension and understanding of consumer communications including prescription and over-the-counter drug labels (Davis *et al.* 2006; Raymond *et al.* 2002; Shiffman *et al.* 2011; Wolf *et al.* 2006) and FDA risk communications (McCormack *et al.* 2016). Consistent with this, respondents with limited health literacy typically showed less understanding of the messages

conveyed by the proposed advertisement, and were consistently more likely than any other subgroup to answer "don't know/not sure" when such options were available. The advertisement text included simple, direct wording, and used devices such as bullet points and white space, that are recommended for effective communication across the spectrum of health literacy (CDC 2009; Plain Language Action and Information Network 2011). The proposed advertisement aims to communicate multiple messages, which can complicate communication, particularly on a single, brief exposure. It may be that repeated and prolonged exposure, or expression of the messages in different ways from different sources, may help communicate the messages to individuals with limited health literacy. In any case, even those with limited health literacy showed reasonable comprehension of key messages, notably *not* being led to think that use of Camel Snus carries no risk, that non-smokers should use Camel Snus, that Camel Snus is not addictive, or that smokers should simply add use of Camel Snus to their smoking. The results suggest that even individuals with limited health literacy would not be put at risk by the proposed advertisement with the modified risk messaging.

Comprehension among ethnic minority respondents was somewhat lower overall than for Caucasian respondents. This may be because of the association between health literacy and minority status. Studies have shown that racial and ethnic minorities, particularly African Americans and Hispanics, have a higher prevalence of limited health literacy (IOM 2004; Kutner *et al.* 2006; Rudd 2007).

6.2.4.3.2 Limitations and Strengths

Like any study, this study had limitations. The sample was drawn from an opt-in online panel, and thus may not be fully representative of the U.S. population, not all of whom have internet access or join online panels. However, strong majorities of Americans are now online (Perrin and Duggan 2015), and online panels can produce reasonable estimates (Farrell and Petersen 2010). Moreover, the sample was diverse, and was recruited and weighted to represent the demographics of the U.S. population.

The proposed Camel Snus advertisement is intended to be displayed in multiple media, but in this study the advertisement was evaluated via an online, on-screen display in a research context. However, such methods are often used to evaluate communications (Sullivan *et al.* 2015), and there is little reason to think the results are not generalizable to other media. The study measured the effects of a single exposure of the proposed modified risk advertising for Camel Snus during the course of a study, as opposed to the effects of multiple exposures over time in the real world in the context of advertising. It is possible that repeated exposure over time to the modified risk advertising would lead to improved comprehension and understanding of the absolute and relative health risks of Camel Snus and cigarette smoking (Borland *et al.* 2012). Nonetheless, the results from this study indicate good comprehension of the proposed modified risk advertising for Camel Snus. The advertisement communicated a great deal of presumably new information about Camel Snus and its risk reduction potential relative to cigarette smoking.

Importantly, some of the information in the proposed advertisement was likely at odds with respondents' pre-existing beliefs, as research consistently shows that people believe that

smokeless tobacco products are at least as hazardous as cigarettes (Fong *et al.* 2016; Kaufman *et al.* 2014; Kiviniemi and Kozlowski 2015; Liu *et al.* 2015; Regan *et al.* 2012; Wray *et al.* 2012). That respondents applied their own beliefs, and not just their understanding of the advertisement, was evident in the pattern of responses, particularly the differentiation of oral cancer risk compared to other risks (*see above*). Thus, some information may have been understood, but not believed (Borland *et al.* 2012). The fact that the source of the information was a tobacco company may have made the information less credible, as tobacco companies now rank as among the least credible information sources (Byrne *et al.* 2012; Harris Interactive 2013). Multiple exposures to relevant messages, and support of messages from multiple credible sources, may help overcome people's current beliefs and misperceptions about smokeless tobacco and snus. Finally, the study itself was long and may have led to respondent fatigue.

The study also had considerable strengths. The sample was large, diverse, and sampled and weighted to match the demographics of U.S. adults. It included a broad range of demographics, including a substantial representation of individuals with limited health literacy. The assessment covered a broad range of messages identified by FDA in its Draft Guidance on MRTPAs, and thus addresses the issues of concern for modified risk messaging. The study sampled current, former, and never users of tobacco products, and also analyzed responses from important subgroups based on demographics or tobacco use history. Survey questions and algorithms used to characterize subgroups were drawn from well-established norms in the published literature. Questions about relative risk of Camel Snus were asked in two different ways, and generated consistent, convergent results.

6.2.4.4 Summary – Execution 1

This study assessed adults' responses to proposed Camel Snus modified risk advertising that carried a risk reduction message, and also conveyed important messages aimed to mitigate potential unintended consequences of modified risk messaging. The results showed that individuals exposed to such messages understood that Camel Snus carries less risk than cigarette smoking, but still carries considerable risk and is not completely safe. They understood that Camel Snus is addictive, that quitting smoking is the best choice, and that persons who do not already use tobacco should not use Camel Snus. In short, the proposed messaging was successful in communicating reduced risk while avoiding over-generalization of the risk messaging and mitigating any potential for the messaging to deter quitting or promote initiation. In sum, the proposed advertising was understood.

6.2.5 Camel SNUS Modified Risk Messaging: Comprehension and Perceptions among Tobacco Users and Non-Users – Second Execution of Consumer Testing

6.2.5.1 Study Methods

Sample

A study was conducted with a sample of 4,924 U.S. adults who, based on age (typically 18+) were legally eligible to purchase tobacco in their state of residence. The sample was drawn randomly

from the Research Now online panel of approximately three million individuals in the U.S. Quota sampling was done to obtain approximately 1,500 respondents each in three tobacco user groups of interest (current tobacco users, former tobacco users, and never tobacco users, described below). Quota sampling was also used to maximize representativeness with respect to gender, age, race/ethnicity, education, and geographic region. Sampling was done to ensure a minimum of 100 respondents in other subgroups of interest, including those with limited health literacy, ethnic minorities, young adults ages 18-24, and white males (who are the primary users of smokeless tobacco [[USDHHS 2014](#)]). Young adults ages 18-24 were analyzed as a subgroup, as a proxy for those under legal purchase age.

The three tobacco user groups of interest were as follows:

1. *Current tobacco users* (n=1,326), defined as those who met historical usage thresholds for at least one tobacco product (*i.e.*, smoked at least 100 cigarettes in lifetime [[Bondy et al. 2009](#)], or ever fairly regularly used any other tobacco product), and used tobacco “every day” or “some days” at the time of the study;
2. *Former tobacco users* (n=1,526), defined as those who met historical usage thresholds for at least one tobacco product, but did not use tobacco at all at the time of the study; and
3. *Never tobacco users* (n=1,500), defined as those who reported having never used tobacco, even once or twice.

An additional sample of experimental tobacco users (n=572) was surveyed to capture those who have used tobacco products but have not become established users. The final sample (n=4,924) was weighted to match the U.S. population in terms of gender, age, race/ethnicity, education, and geographic region. A detailed description of the sampling plan and weighting is available in the study protocol ([Protocol Identifier: RO-BR-2015-02 Camel Snus Modified Risk Messaging: Comprehension and Perceptions among Tobacco Users and Non-Users – Second Execution of Consumer Testing](#)) and the final study report ([Camel SNUS Modified Risk Messaging: Comprehension and Perceptions among Tobacco Users and Non-Users – Second Execution of Consumer Testing – Amended Final Report](#)), respectively.

Additional subgroups

Consistent with the tobacco literature ([CDC 1994](#)), established tobacco users (current and former users) were identified based on having achieved a sufficiently high level of use to qualify as established users. For example, based on the literature ([Bondy et al. 2009](#)), those who have not smoked at least 100 cigarettes in their lifetime have not become established smokers. These individuals, however, could eventually progress to current smoking. To capture those who have used tobacco products but have not become established users, an additional sample of 572 experimental tobacco users (referred to as “experimenters”) was surveyed. For the purposes of this study, experimenters were defined as those who reported (a) having ever used a tobacco product, even once or twice; (b) not meeting historical usage thresholds for any tobacco product

to be considered a “regular” user; and (c) use of tobacco “every day” or “some days” at the time of the study.

In addition, “potential quitters” (n=313) were identified among current tobacco users. For the purposes of this study, potential quitters were defined as those who (a) reported having stopped use of tobacco for one day or longer in the past 12 months in an effort to quit tobacco completely; (b) indicated they wanted to quit using tobacco “somewhat” or “a lot”; (c) rated the likelihood of trying to quit tobacco in the next 30 days as “somewhat” or “very” likely; and (d) rated the likelihood of being successful in quitting tobacco as “somewhat likely” or “very likely” if a quit attempt was made. Individuals who meet these criteria are considered more likely to quit tobacco use (Sciamanna *et al.* 2000) and are an important subgroup in which to examine the effects of the proposed modified risk advertising for Camel Snus.

Procedures

The online study was conducted June 24, 2015 to July 21, 2015. Respondents were screened for demographics and use of tobacco products (for the screener, see [Protocol Identifier: RO-BR-2015-02 Camel Snus Modified Risk Messaging: Comprehension and Perceptions among Tobacco Users and Non-Users – Second Execution of Consumer Testing](#)). Qualified respondents were shown the proposed Camel Snus modified risk advertisement that included proposed modified risk messaging. The advertisement consisted of three separate color images that appeared one above the other on the same screen. The bottom fifth of each image included one of four government-mandated warning label statements, randomly rotated for study respondents (for the advertisements viewed by respondents, see [Protocol Identifier: RO-BR-2015-02 Camel Snus Modified Risk Messaging: Comprehension and Perceptions among Tobacco Users and Non-Users – Second Execution of Consumer Testing](#)). The proposed modified risk advertising included the following statements (verbatim):

- Smokers who switch completely from cigarettes to Camel Snus can greatly reduce their risk of lung cancer, oral cancer, respiratory disease, and heart disease.
- No smoke = less risk.
- Scientific studies have shown that Camel Snus contains less of the harmful chemicals than cigarette smoke.
- Switching to snus means less risk for you and those around you.
- Switch completely from cigarettes to Camel Snus.
- No tobacco product is safe.
- 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.

- But if you're not going to quit using tobacco products, you should think about switching to Camel Snus.

Following exposure to the advertisement, respondents were asked questions to assess their comprehension and perceptions of the absolute health risks of Camel Snus, as well as health risks relative to cigarette smoking, cessation aids, and quitting all tobacco use (for the survey, see [Protocol Identifier: RO-BR-2015-02 Camel Snus Modified Risk Messaging: Comprehension and Perceptions among Tobacco Users and Non-Users – Second Execution of Consumer Testing](#)). Respondents could view the advertisement and refer to it at any time during the study. The survey questions appeared on the same screen directly below the advertisement, allowing respondents to scroll between the questions and the advertisement as desired. Questions posed to respondents were adapted from published studies that addressed health risk beliefs and risk perceptions of different types of tobacco products (e.g., [Haddock et al. 2004](#); [O'Connor et al. 2005a](#); [Peiper et al. 2010](#)). At the end of the study, a health literacy test (i.e., Newest Vital Sign, NVS) ([Weiss et al. 2005](#)) was completed by all respondents. This test assesses literacy based on respondents' ability to interpret an FDA food label.

Analysis

For the sample as a whole, and for various subgroups, responses to questions addressing the major communications objectives were summarized descriptively by means and 95% confidence intervals (for numerical ratings) or percentages and 95% confidence intervals (for categorical variables). No tests of statistical significance were conducted. For questions about comparative risks of Camel Snus and cigarette smoking, the proportion of respondents indicating that Camel Snus had at least some risk was computed by combining those who stated that Camel Snus has the same risk as smoking and those who stated that Camel Snus has less risk than smoking but still has some risk. All data were averaged across the sub-samples that each saw one of four randomly-rotated government-mandated smokeless tobacco warning label statements.

6.2.5.2 Study Results

The results of the “Camel SNUS Modified Risk Messaging: Comprehension and Perceptions among Tobacco Users and Non-Users – Second Execution of Consumer Testing” study are summarized below. The results are presented for the full sample overall, as well as the particular subgroups for which a specific modified risk message is most relevant (e.g., messaging about quitting tobacco use for current tobacco users, messaging about the health risks of Camel Snus relative to quitting all tobacco use for current tobacco users and potential quitters). In addition, results for certain populations, including minorities and those with limited health literacy, are reported where there are material differences.

The final study report for this study is submitted with this Application and includes the complete tabulation of study results and findings for each of the subgroups of interest (i.e., current tobacco users, former tobacco users, never tobacco users, experimenters, potential quitters, those with limited health literacy, minorities, young adults ages 18-24, and white males) ([Camel SNUS Modified Risk Messaging: Comprehension and Perceptions among Tobacco Users and Non-Users](#)

– [Second Execution of Consumer Testing – Amended Final Report](#)). All results for each subgroup are not repeated in this summary; however, ranges across groups, and particular subgroup results are discussed when particularly relevant or where there are material differences.

6.2.5.2.1 Demographics

Among the 4,924 respondents, 27% (n=1,326) were current tobacco users, 31% (n=1,526) were former tobacco users, and 30% (n=1,500) were never tobacco users, and 12% (n=572) were experimenters. Among the current tobacco users, 75% were current cigarette smokers⁴ (58% every day; 17% some days), 6% were current snus users, and 10% used other forms of smokeless tobacco. A total of 8% were current users of more than one tobacco product. Respondents were 18 and older, including 16% aged 18-30, 36% aged 31-50, and 48% aged 51 and older. The sample was 50% female; 30% had a high school education, 34% completed some college, and 36% had a bachelor's or advanced degree. The majority of the sample was non-Hispanic Caucasian (76%), 9% were of Hispanic, Latino, or Spanish origin, 8% were non-Hispanic African American, and 7% were non-Hispanic Asian or other race. In terms of geographic distribution, 34% were from the South, 22% from the West, 23% from the Midwest, and 21% from the Northeast. The weighted demographic profile of the full sample was comparable to the U.S. population overall (for the demographic profile of the sample by tobacco user group, see Table 2 [unweighted data] and Table 6 [weighted data] in [Camel SNUS Modified Risk Messaging: Comprehension and Perceptions among Tobacco Users and Non-Users – Second Execution of Consumer Testing – Amended Final Report](#)). A total of 35% of the overall sample was assessed to have limited health literacy, based on the NVS test.⁵

6.2.5.2.2 Respondents' beliefs about the health risks of Camel Snus relative to cigarette smoking, and Camel Snus absolute risks

The FDA MRTPA Draft Guidance indicates that a critical issue to address is consumers' beliefs about the health risks of the MRTP relative to cigarette smoking. Ideally, consumers should understand that the MRTP (Camel Snus) carries lower risk than cigarette smoking for certain diseases, but they should not view the MRTP (Camel Snus) as being completely safe or free of risk.

Respondents' understanding of the risks of Camel Snus relative to cigarette smoking was evaluated in two ways: through comparison of quantitative ratings of risk for each product, and

⁴ Respondents were considered cigarette smokers if they smoked manufactured cigarettes. Only 0.5% (n=27) of respondents indicated smoking roll-your-own cigarettes; these were counted as tobacco users but not cigarette smokers.

⁵ Consistent with findings from other studies (IOM 2004; Kutner *et al.* 2006; Rudd 2007), there were substantial variations in assessed health literacy by ethnicity in this study, with African American (61%) and Hispanic (47%) respondents more likely to be assessed as having limited health literacy than Caucasian (30%), Asian (40%), or other respondents (38%). Overall, 49% of minority (non-Caucasian) respondents scored as having limited health literacy. This likely affects comparisons of comprehension by ethnicity.

by asking respondents to directly characterize qualitatively the risk of Camel Snus relative to smoking.

Quantitative ratings of risk

As one way to capture perceptions of risk, respondents were asked to rate (on a 7-point scale ranging from “no risk” to “substantial risk”) the impact of Camel Snus and cigarette smoking on the risk of developing the four diseases specifically mentioned in the proposed advertisement (*i.e.*, lung cancer, respiratory disease, heart disease, and oral cancer) (Questions 2a-2d on the survey; [Protocol Identifier: RO-BR-2015-02 Camel Snus Modified Risk Messaging: Comprehension and Perceptions among Tobacco Users and Non-Users – Second Execution of Consumer Testing](#)).

Table 6.2.5-1 below summarizes respondents’ beliefs about the health risks associated with Camel Snus and cigarette smoking. Overall, mean risk ratings for Camel Snus for the four diseases specifically mentioned in the advertisement were always lower than those for cigarette smoking, demonstrating that respondents correctly understood the proposed advertising message that Camel Snus presents less risk than cigarette smoking. Notably, the rated difference in risk was highest for respiratory conditions (lung cancer and respiratory disease) and lowest for oral cancer.

At the same time, respondents also understood that Camel Snus nevertheless carried some risk, as is evident from the risk ratings they assigned to Camel Snus on the 1 to 7 scale (Table 6.2.5-1 below). Mean risk ratings for Camel Snus ranged from 4.6 for respiratory disease to 5.7 for oral cancer. Importantly, all Camel Snus risk ratings fell above the midpoint of the 1-7 scale. For comparison, risk ratings for cigarette smoking ranged from 6.2 to 6.6. Therefore, respondents also understood that Camel Snus does pose *at least some risk* for each disease, and that risk is not zero (*i.e.*, no risk at all).

Table 6.2.5-1: Respondents’ (n=4,924) Beliefs about the Health Risks of Camel Snus, Cigarette Smoking, and Smokeless Tobacco

	Camel Snus	Cigarette Smoking	Smokeless Tobacco (other than Camel Snus)
Risk of developing lung cancer*	4.8** (4.74-4.86)	6.6 (6.56-6.64)	5.2 (5.14-5.26)
Risk of developing respiratory disease	4.6 (4.54-4.66)	6.5 (6.46-6.54)	5.1 (5.04-5.16)
Risk of developing heart disease	5.3 (5.24-5.36)	6.4 (6.36-6.44)	5.6 (5.55-5.65)
Risk of developing oral cancer	5.7 (5.64-5.76)	6.2 (6.15-6.25)	6.1 (6.05-6.15)

* Rated on a 7-point scale ranging from 1 (“no risk”) to 7 (“substantial risk”)

** Mean risk rating (95% confidence interval in parentheses)

Indeed, the numerical ratings give some insight into the degree of risk reduction that respondents assumed for Camel Snus compared to smoking. The mean ratings for cigarette

smoking are quite high, near the top limit of the scale (designated as "substantial risk"). The estimates for Camel Snus were lower, but very modestly so⁶. Even for lung cancer and respiratory disease, respondents on average attributed very substantial risks to use of Camel Snus.

Subgroups of interest

Consistent with the results for the full sample, across each of the subgroups (including limited health literacy and minority respondents) the mean risk ratings for Camel Snus for the four diseases were always lower than those for cigarette smoking ([Appendix B, Table 4](#) and [Table 5](#) in *Camel SNUS Modified Risk Messaging: Comprehension and Perceptions among Tobacco Users and Non-Users – Second Execution of Consumer Testing – Amended Final Report*). This suggests all subgroups understood that Camel Snus poses less risk than cigarette smoking.

The mean risk ratings for all subgroups also indicated understanding that Camel Snus does carry some risk of each disease. Even the lowest mean risk rating assigned to any one disease (respiratory disease) reflected an expectation of significant risk across all subgroups (*e.g.*, current tobacco users [4.0; 95% confidence interval =3.87-4.13], former tobacco users [4.4; 4.30-4.50], never tobacco users [5.0; 4.90-5.10], experimenters [4.4; 4.18-4.62], and young adults ages 18-24 [4.6; 4.30-4.90]). The perceived risk rating was highest for oral cancer across all subgroups (*e.g.*, current tobacco users [5.5; 5.42-5.58], former tobacco users [5.8; 5.71-5.89], never tobacco users [5.8; 5.71-5.89], experimenters [5.4; 5.20-5.62], and young adults ages 18-24 [5.6; 5.35-5.85] (for detailed results for the subgroups, see [Appendix B, Table 4](#) in *Camel SNUS Modified Risk Messaging: Comprehension and Perceptions among Tobacco Users and Non-Users – Second Execution of Consumer Testing – Amended Final Report*).

Qualitative characterization of risk

In another risk perception question, respondents were asked specifically to characterize the level of risk of using Camel Snus as (a) reduced relative to smoking, (b) similar to that of smoking, (c) having no risk at all, or (d) don't know/not sure response option. These judgments were made separately with respect to lung cancer, respiratory disease, heart disease, and oral cancer; Question 1b on the survey).

[Table 6.2.5-2](#) below summarizes respondents' understanding of the risk reduction of Camel Snus compared to continued smoking. Respondents were very consistent in their responses across the four different disease risks specifically mentioned in the proposed advertisement.

⁶ It is possible to calculate crude estimates of the relative reduction in risk from the 1-7 risk ratings made by respondents. The ratings were scaled such that 1 = "no risk." Subtracting 1 from the ratings thus sets 0 equal to "no risk," allowing crude computations of risk reduction implied by the ratings, and expressing the risk attributed to Camel Snus as a percentage of that attributed to smoking. On this basis, the respondents' ratings of Camel Snus versus smoking imply a 32% risk reduction for lung cancer, a 35% risk reduction for respiratory disease, a 20% reduction for risk of heart disease, and a 10% risk reduction for oral cancer. These implied risk reductions are much more modest than those derived from expert consensus [[Levy et al. 2004](#); [Nutt et al. 2014](#)], which imply roughly 90% risk reduction.

About two-thirds indicated that compared to smoking, Camel Snus has less risk of lung cancer (62%), respiratory disease (61%), and heart disease (58%); the percentage was somewhat lower for oral cancer (52%). Across all four diseases, 9-12% of respondents indicated they did not know or were not sure what the risk of Camel Snus was relative to cigarette smoking.

The basic risk reduction message was not understood, or not believed, by some respondents, such that 20% and 21%, respectively, reported that Camel Snus poses the same risk of lung cancer and respiratory disease as cigarette smoking; 25% believed that Camel Snus poses the same risk of heart disease; and 37% believed that Camel Snus posed the same risk of oral cancer as cigarette smoking.

Approximately 10% of respondents did not know or were not sure what the risk of Camel Snus was, whether on an absolute or relative basis.

Consistent with the quantitative ratings, few respondents believed that Camel Snus had no risk at all. This risk characterization was endorsed by less than 10% of respondents, across diseases. This figure was lowest for oral cancer, at 3%. Similarly, 82%-89% indicated that Camel Snus carries at least some risk for each disease. This suggests that respondents understood that Camel Snus is not risk-free and still poses some risk.

Table 6.2.5-2: Respondents’ (n=4,924) Understanding of the Health Risks of Camel Snus Relative to Continuing to Smoke

	Same risk as continuing to smoke	Less risk than continuing to smoke, but some risk	Net “some risk”	No risk at all	Don’t know / Not sure
Lung cancer risk	20% (18.5%-21.5%)*	62% (60.3%-63.7%)	82% (80.6%-83.4%)	9% (8.0%-10.0%)	9% (7.9%-10.1%)
Respiratory disease risk	21% (19.5%-22.5%)	61% (59.3%-62.7%)	82% (80.6%-83.4%)	8% (7.0%-9.0%)	10% (8.9%-11.1%)
Heart disease risk	25% (23.5%-26.5%)	58% (56.3%-59.7%)	83% (81.6%-84.4%)	6% (5.2%-6.8%)	12% (10.8%-13.2%)
Oral cancer risk	37% (35.3%-38.7%)	52% (50.2%-53.8%)	89% (87.8%-90.2%)	3% (2.4%-3.6%)	9% (7.9%-10.1%)

*95% confidence interval

Subgroups of interest

Among current tobacco users – a subgroup for whom the modified risk advertising is particularly relevant – at least 80% stated that Camel Snus is associated with some risk of each disease. For oral cancer, only 4% (2.8%-5.2%) of current tobacco users stated that Camel Snus was associated with no risk, whereas this figure was 14% (11.8%-16.2%) for lung cancer and respiratory disease, respectively (for detailed results across the subgroups, see [Appendix A, Table 3](#) in Camel SNUS Modified Risk Messaging: Comprehension and Perceptions among Tobacco Users and Non-Users – Second Execution of Consumer Testing – Amended Final Report). Similarly, among potential

quitters – another subgroup for whom this message is highly relevant – at least 82% stated that Camel Snus is associated with some risk of each disease. Again, only 5% (1.9%-8.1%) reported no risk for oral cancer, while 12% (7.6%-16.4%) reported no risk for respiratory disease, and 11% (6.9%-15.1%) reported no risk for lung cancer.

As expected, those with limited health literacy demonstrated lower overall comprehension of or belief in the risk reduction messaging, relative to all other respondents. For each of the four diseases, less than 50% of those with limited health literacy correctly indicated Camel Snus poses less risk than smoking, while 33% to 44% indicated equal risk for Camel Snus and smoking. However, consistent with the responses of all other respondents, less than 10% of limited health literacy respondents incorrectly indicated that the advertisement conveyed no risk at all with Camel Snus for each of the diseases ([Appendix A, Table 3](#) in Camel SNUS Modified Risk Messaging: Comprehension and Perceptions among Tobacco Users and Non-Users – Second Execution of Consumer Testing – Amended Final Report), suggesting that this misperception was not prevalent even among those who may have had trouble understanding the messaging.

Among minority (*i.e.*, non-Caucasian) respondents, at least 79% stated that Camel Snus is associated with some risk of each disease. Only 4% (2.6%-5.4%) (for oral cancer), 6% (4.2%-7.8%) (for heart disease), and 8% (6.1%-9.9%; 6.0%-10.0%) (for lung cancer and respiratory disease, respectively) incorrectly indicated no risk at all, again suggesting understanding of this aspect of the message. In no subgroup examined did the percentage of respondents believing Camel Snus posed no risk at all exceed 14% (this was the highest percentage, among current tobacco users, for risk of lung cancer and respiratory disease, respectively).

6.2.5.2.3 Perceptions of risk across the diseases mentioned in the proposed advertisement

The proposed advertisement mentioned reduced risk of lung cancer, respiratory disease, heart disease, and oral cancer. Although the proposed advertisement did not explicitly distinguish the relative risk for these four conditions, respondents appeared to do so in their ratings of risk. Respondents consistently rated the risk of oral cancer higher than that of the respiratory conditions – in quantitative ratings using the 1 to 7 scale ([Table 6.2.5-1](#) above), the risk of oral cancer was rated at 5.7, whereas the risk of lung cancer was rated 4.8 and respiratory disease was rated 4.6. The risk of heart disease was intermediate at 5.3. Similarly, in qualitative ratings ([Table 6.2.5-2](#) above), 37% thought the risk of Camel Snus for oral cancer was the same as that associated with continuing to smoke; in contrast, this figure was 20% for lung cancer, 21% for respiratory disease, and 25% for heart disease. Conversely, whereas 8-9% believed that Camel Snus carried no risk at all for respiratory disease and lung cancer, only 3% saw no risk for oral cancer and 6% saw no risk for heart disease.

This pattern of beliefs about risk corresponds to that seen in recent qualitative research on the public's perceptions of snus ([Choi et al. 2012](#)), where respondents inferred oral cancer risk from the fact that oral tobacco products come into direct contact with the mouth. That the results in the present comprehension and perceptions study mirrored those results indicates that respondents' stated risk perceptions were partly influenced by their pre-existing beliefs or

assumptions, even though respondents were asked to respond according to the information presented in the proposed advertisement.

Subgroups of interest

Each of the different subgroups rated the risk of oral cancer higher than that of the respiratory conditions in the quantitative assessment of risk ([Appendix B, Table 4](#) in Camel SNUS Modified Risk Messaging: Comprehension and Perceptions among Tobacco Users and Non-Users – Second Execution of Consumer Testing – Amended Final Report). The lowest mean risk rating was always assigned to respiratory disease across all subgroups (mean ratings ranged from 4.0 to 5.0), but such ratings still reflect a perception of some risk posed by Camel Snus.

In the qualitative assessment of risk ([Appendix A, Table 3](#) in Camel SNUS Modified Risk Messaging: Comprehension and Perceptions among Tobacco Users and Non-Users – Second Execution of Consumer Testing – Amended Final Report), the percentage of respondents in each subgroup indicating that Camel Snus posed no risk at all was always highest for lung cancer or respiratory disease risk, and lowest for oral cancer risk, consistent with the trends in the sample as a whole, and with trends seen in the published literature on the public’s risk perceptions about smokeless tobacco and snus compared to cigarettes ([Choi et al. 2012](#); [Pepper et al. 2015](#); [Wray et al. 2012](#)). Across all subgroups, at least 75% indicated that Camel Snus is associated with some risk of each of the four diseases (*e.g.*, 80% for current tobacco users, 84% for former tobacco users, and 79% for minority respondents), and the percentage of respondents believing that Camel Snus posed at least some risk was always highest for oral cancer (*e.g.*, 91% for current tobacco users, 91% for former tobacco users, and 86% for minority respondents).

6.2.5.2.4 Respondents’ Understanding of Relative Risks for Diseases Not Mentioned in the Proposed Advertisement

It was conceivable that respondents might generalize the information provided in the proposed modified risk advertisement to apply to diseases not explicitly mentioned. To assess for such generalization, a question was posed regarding the risk reduction potential of Camel Snus for other diseases *not mentioned in the advertisement* (Question 2g on the survey).

Across all respondents, 17% (15.7%-18.3%) believed that “Camel Snus reduces the risk of other smoking-related diseases that are not discussed in the ad” (yes/no/don’t know response options); 35% (33.3%-36.7%) indicated ‘no’, but most (48%; 46.2%-49.8%) were understandably unsure. Although some generalization is likely reasonable, the data suggest that the messaging did not lead respondents to make sweeping generalizations or draw strong conclusions about diseases not explicitly mentioned in the proposed advertisement ([Table 9](#) in Camel SNUS Modified Risk Messaging: Comprehension and Perceptions among Tobacco Users and Non-Users – Second Execution of Consumer Testing – Amended Final Report).

Subgroups of interest

The results for the diseases “not mentioned in the advertisement” question for the different subgroups were similar to those for all respondents (Appendix B, Table 7 in Camel SNUS Modified Risk Messaging: Comprehension and Perceptions among Tobacco Users and Non-Users – Second Execution of Consumer Testing – Amended Final Report). Those who reported that Camel Snus reduced the risk of other diseases not mentioned in the advertisement ranged from a low of 15% for never tobacco users to a high of 26% for potential quitters. In addition, 31-41% in each subgroup indicated ‘no’, and 40-52% were unsure. Of interest, among all of the different subgroups, those most likely to say that Camel Snus did not reduce the risk of diseases not mentioned in the advertisement included those with limited health literacy (41%; 38.0%-44.0%), young adults (40%; 32.3%-47.7%), and never tobacco users (38%; 35.3%-40.7%).

6.2.5.2.5 Respondents’ Beliefs about the Risk of Developing Generally Poorer Health

Respondents were also asked to rate the impact of Camel Snus, cigarette smoking, and smokeless tobacco use (other than Camel Snus) on risk of “developing generally poorer health”, using the same scale used to rate Camel Snus and cigarette smoking (a 7-point scale ranging from “no risk” to “substantial risk”; Question 2e on the survey). The proposed advertisement did not include any specific reference to overall health, but mentioned four serious diseases (lung cancer, oral cancer, respiratory disease, and heart disease) that might be taken as relevant to overall health status.

Table 6.2.5-3 below shows respondents’ mean risk ratings for the risk of developing poorer health for Camel Snus and cigarette smoking. The ratings show that the risk for Camel Snus (5.7) is rated as lower than that of cigarette smoking (6.5). The risk rating assigned to Camel Snus for overall health was higher than that assigned to it for risk of lung cancer, respiratory disease, and heart disease, and the same as that assigned for oral cancer (Table 6.2.5-1 above). The ratings suggest that respondents believed that Camel Snus carries considerable risk to overall health, though not as high a risk as smoking does.

Table 6.2.5-3: Respondents’ (n=4,924) Beliefs about the Risk of Developing Poorer Health for Camel Snus, Cigarette Smoking, and Smokeless Tobacco

	Camel Snus	Cigarette Smoking	Smokeless Tobacco (other than Camel Snus)
Risk of developing generally poorer health	5.7 (5.64-5.76)	6.5 (6.46-6.54)	6.0 (5.95-6.05)

* Rated on a 7-point scale ranging from 1 (“no risk”) to 7 (“substantial risk”)

** Mean risk rating (95% confidence interval in parentheses)

Subgroups of interest

The results across the subgroups for ratings of risk of developing generally poorer health were consistent with those for the full sample – for each subgroup, the mean risk ratings for Camel Snus (range = 5.2-5.9) were always lower than those for cigarette smoking (range = 6.0-6.6) (Appendix B, Tables 4 and 5 in Camel SNUS Modified Risk Messaging: Comprehension and

Perceptions among Tobacco Users and Non-Users – Second Execution of Consumer Testing – Amended Final Report). In addition, across each of the different subgroups, the risk rating assigned to Camel Snus for overall health was higher than that assigned to it for risk of lung cancer, respiratory disease, and heart disease, and very similar (though sometimes slightly lower or higher) than that assigned for oral cancer.

6.2.5.2.6 Respondents’ Beliefs about the Health Risks of Camel Snus Relative to Smokeless Tobacco

In addition to assessing comprehension of how the risk of Camel Snus compares with cigarette smoking, FDA’s MRTPA Draft Guidance recommends that applicants also assess perceptions of risk for the MRTP compared to other tobacco products in the same class. Accordingly, respondents were also asked to rate the impact of smokeless tobacco use (other than Camel Snus) on the risk of developing the four diseases specifically mentioned in the proposed advertisement (*i.e.*, lung cancer, oral cancer, respiratory disease, and heart disease), using the same scale used to rate Camel Snus and cigarette smoking (a 7-point scale ranging from “no risk” to “substantial risk”; Questions 2a-2d on the survey).

[Table 6.2.5-1](#) above summarizes respondents’ ratings of the health risks associated with Camel Snus and smokeless tobacco use. The ratings show that the risks of other smokeless tobacco products are rated higher than that of Camel Snus for each of the four diseases, with the difference between Camel Snus and other smokeless tobacco products being consistently smaller than that between Camel Snus and cigarette smoking. Mean risk ratings for cigarette smoking were always the highest. These results suggest good comprehension of the modified risk advertising – respondents reported that other smokeless tobacco products pose more risk of the four diseases than Camel Snus. In a similar vein, as seen in [Table 6.2.5-3](#), the risk of other smokeless tobacco on "generally poorer health" was rated higher than the risk of Camel Snus (6.0 vs. 5.7), but lower than the risk of cigarette smoking (6.5). This suggests that respondents did not generalize the modified risk advertising to all smokeless tobacco products.

Subgroups of interest

Consistent with the results for the full sample, across each of the subgroups (including those with limited health literacy and minority respondents) the mean risk ratings for other smokeless tobacco for the four diseases were always higher than those for Camel Snus ([Appendix B, Tables 4 and 6](#) in Camel SNUS Modified Risk Messaging: Comprehension and Perceptions among Tobacco Users and Non-Users – Second Execution of Consumer Testing – Amended Final Report). This suggests all subgroups perceived that other smokeless tobacco poses more risk than Camel Snus, and that the modified risk advertising was not generalized to all smokeless tobacco.

6.2.5.2.7 Respondents’ Beliefs about the Health Risks of Camel Snus Relative to Smoking Cessation Aids

Because FDA’s MRTP Draft Guidance recommends that perceived risk be evaluated in comparison to therapeutic nicotine replacement products, respondents were asked about the health risks of

Camel Snus compared to nicotine replacement products (Question 5a on the survey). There was no mention of cessation products or other nicotine products in the proposed advertisement. Across all respondents, 63% (61.3%-64.7%) endorsed the statement that “Camel Snus is NOT a safer alternative than products that are used to quit tobacco such as gum, patches, and lozenges” (respondents were asked to identify the true statement). The remaining respondents considered the statement untrue (12%; 10.9%-13.1%) or were unsure of the correct response (25%; 23.5%-26.5%), as this issue was not directly addressed in the proposed advertisement. A possible explanation for incorrect responses (*i.e.*, cessation products are not safer than Camel Snus) could be that respondents, like many in the population, had pre-existing misperceptions about the safety of nicotine replacement therapies (NRTs). Studies have demonstrated widespread misperceptions about the safety and addictive potential of NRT overall and relative to cigarettes (Ferguson *et al.* 2011; Shiffman *et al.* 2008; Silla *et al.* 2014).

Subgroups of interest

Among potential quitters, for whom NRT would be an appropriate consideration, 58% (51.2%-64.8%) endorsed the statement (*i.e.*, Camel Snus is not a safer alternative than products used to quit tobacco), while 27% (20.6%-33.4%) did not, and 15% (10.2%-19.8%) were unsure whether Camel Snus is a safer alternative than nicotine replacement products. Those with limited health literacy were the subgroup most likely to indicate that they did not know the answer (32%; 29.1%-34.9%) and were the lowest proportion endorsing the statement (50%; 47.0%-53.0%). Across the different subgroups, 18-24-year-olds were most likely to endorse the statement (69%; 61.7%-76.3%) (for detailed results across the different subgroups, see [Table 9](#) and [Appendix B, Table 8](#) in Camel SNUS Modified Risk Messaging: Comprehension and Perceptions among Tobacco Users and Non-Users – Second Execution of Consumer Testing – Amended Final Report).

6.2.5.2.8 Respondents’ Beliefs about the Health Risks of Camel Snus Relative to Quitting All Tobacco Use

In accordance with the Draft Guidance for MRTPAs, respondents were also asked about the safety of Camel Snus relative to stopping use of all tobacco products (Question 5b on the survey). Although the proposed advertisement did not explicitly state that cessation of all tobacco use is safer than Camel Snus, it did state “*If you’re a smoker concerned about the health risks from smoking, the best choice is to quit*” and “*No tobacco product is safe.*” (Italics added.) In addition, one-quarter of the full sample viewed a proposed advertisement with the government-mandated warning label statement “WARNING: This product is not a safe alternative to cigarettes.”

Across all respondents, 70% (68.4%-71.6%) correctly responded that “Camel Snus is NOT a safer alternative than quitting tobacco entirely”; 14% (12.8%-15.2%) answered incorrectly, and 16% (14.6%-17.4%) were unsure of the correct response.

Subgroups of interest

Among current tobacco users and potential quitters – two subgroups for whom this particular message is most relevant – 67% (64.0%-70.0%) and 64% (57.5%-70.5%) answered correctly, approximately one-quarter in each of these groups (22% [19.3%-24.7%] and 26% [20%-32%]) answered incorrectly, and 11% (9.0%-13.0%) and 10% (6.0%-14.0%) were unsure of whether Camel Snus is a safer alternative to quitting all tobacco use.

Comprehension of this message (*i.e.*, quitting all tobacco use is safer than Camel Snus) is also important for former tobacco users who might be tempted to resume tobacco use with Camel Snus. In this group, 74% (71.4%-76.6%) answered correctly, 14% (12.0%-16.0%) answered incorrectly, and 12% (10.0%-14.0%) were unsure of the correct response. Those with limited health literacy had the lowest proportion of correct responses (55%; 52.0%-58.0%) and the highest proportion of “don’t know/unsure” responses (27%; 24.2%-29.8%) (Table 9 and Appendix B, Table 9 in Camel SNUS Modified Risk Messaging: Comprehension and Perceptions among Tobacco Users and Non-Users – Second Execution of Consumer Testing – Amended Final Report).

6.2.5.2.9 Respondents’ Beliefs about the Addictiveness of Camel Snus

6.2.5.2.9.1 Respondents’ Understanding of the Proposed Advertising – Camel Snus is Addictive

Respondents’ perceptions about the addictiveness of Camel Snus were assessed in two ways: a dichotomous qualitative question, and a quantitative rating question.

Qualitative assessment

Respondents’ understanding that Camel Snus is addictive was assessed in a question that simply asked “Is Camel Snus, which contains nicotine, addictive?” (yes/no/don’t know response options; Question 1a on the survey). Among all respondents, 82% (80.6%-83.4%) correctly stated that Camel Snus is addictive. Most of the remainder (12%; 10.8%-13.2%) were unsure of the correct response, while 6% (5.1%-6.9%) indicated it is not addictive.

Subgroups of interest

Across the subgroups, those with limited health literacy had the lowest proportion of correct responses for this particular question (66%; 63.1%-68.9%) and the highest proportion of “don’t know” responses (21%; 18.5%-23.5%) as well as incorrect responses (13%; 10.8%-15.2%). Given the prominent and explicit statements in the proposed advertisement regarding the addictive potential of Camel Snus that were virtually identical to the question itself, as well as the government-mandated addiction warning label statement displayed to one-quarter of participants, it is unclear why some respondents answered incorrectly or were unsure of the correct response.

Among young adults ages 18-24, 88% (82.6%-93.4%) answered correctly and equal proportions were unsure of the correct response (6%; 2.1%-9.9%) or answered incorrectly (6%; 2.1%-9.9%).

Understanding that Camel Snus is addictive is also important for experimenters, who may ultimately progress to regular tobacco use – 76% (71.0%-81.0%) answered correctly, 12% (7.9%-16.1%) answered incorrectly, and 12% (8.4%-15.6%) were unsure of the correct response (for detailed results across the different subgroups, see [Table 8](#) and [Appendix A](#) in Camel SNUS Modified Risk Messaging: Comprehension and Perceptions among Tobacco Users and Non-Users – Second Execution of Consumer Testing – Amended Final Report).

Quantitative assessment

An additional assessment of the perceived addictiveness of Camel Snus was obtained by asking respondents to quantitatively rate the addictive potential of Camel Snus on a 1-7 scale ranging from “not at all addictive” to “extremely addictive” (Question 2f on the survey).

As shown in [Table 6.2.5-4](#), respondents rated the addictiveness of Camel Snus at 6.1 on the 7-point scale, indicating a substantial degree of perceived addictiveness. Indeed, this risk rating was higher than the ratings assigned by respondents for perceived risk of the four diseases for which reduced risk was claimed ([Table 6.2.5-1](#) above).

Table 6.2.5-4: Respondents’ (4,924) Beliefs about the Addictiveness of Camel Snus, Cigarette Smoking, and Smokeless Tobacco

	Camel Snus	Cigarette Smoking	Smokeless Tobacco (other than Camel Snus)
How addictive *	6.1** (6.05-6.15)	6.6 (6.56-6.64)	6.3 (6.26-6.34)

* Rated on a 7-point scale ranging from 1 (“not at all addictive”) to 7 (“extremely addictive”)

** Mean risk rating (95% confidence interval in parentheses)

Subgroups of interest

The ratings of addictiveness of Camel Snus across subgroups were consistent with those for the full sample – each subgroup, respectively, rated the addictive potential of Camel Snus as high – 6.1 (5.89-6.31) for young adults ages 18-24; 6.1 (6.02-6.18) for never tobacco users; 5.6 (5.43-5.77) for experimenters; and 5.6 (5.49-5.71) for those with limited health literacy (for detailed results across the different subgroups, see [Table 9](#) and [Appendix B, Table 4](#) in Camel SNUS Modified Risk Messaging: Comprehension and Perceptions among Tobacco Users and Non-Users – Second Execution of Consumer Testing – Amended Final Report).

6.2.5.2.9.2 Respondents’ Beliefs about the Addictiveness of Camel Snus Relative to Cigarette Smoking and Other Smokeless Tobacco Products

Respondents were also asked to give quantitative ratings of the addictive potential of cigarette smoking and other smokeless tobacco use, which allowed for assessment of respondents’ perceptions of relative addictiveness. The ratings were made on a 1-7 scale ranging from “not at all addictive” to “extremely addictive” (Question 2f on the survey). The proposed advertisement

seen by respondents explicitly stated that Camel Snus is addictive, but did not provide comparative information on addiction relative to cigarette smoking or other smokeless tobacco.

As shown in [Table 6.2.5-4](#) above, respondents rated the addictiveness of Camel Snus as lower than that of other smokeless tobacco products and cigarette smoking, respectively. The perception of slightly lower addictive potential was modest, amounting to 0.5 points on the 7-point scale when compared to smoking, and 0.2 points on that scale when compared to other smokeless tobacco products.

Subgroups of interest

As in the full sample, the perceived addictiveness of Camel Snus was always rated lower than that of cigarette smoking and other smokeless tobacco across each of the different subgroups. The ratings suggest that respondents believed that Camel Snus is clearly addictive, though slightly less addictive than either cigarette smoking or other smokeless tobacco use ([Appendix B, Tables 4, 5, and 6](#) in *Camel SNUS Modified Risk Messaging: Comprehension and Perceptions among Tobacco Users and Non-Users – Second Execution of Consumer Testing – Amended Final Report*).

6.2.5.2.10 Additional Messages in the Interest of Public Health

6.2.5.2.10.1 Respondents' Understanding of the Proposed Advertising – Switching Completely to Camel Snus to Reduce Health Risks

The reduction of risk associated with switching from cigarette smoking to Camel Snus is best achieved by switching completely from smoking to Camel Snus. To communicate this concept, the proposed modified risk advertisement stated *“Smokers who switch completely from cigarettes to Camel Snus can greatly reduce their risk of lung cancer, oral cancer, respiratory disease, and heart disease.”* In addition, other statements in the proposed advertisement stress “switching” to Camel Snus: *“Switch completely from cigarettes to Camel Snus”; “I’m a smoker. Why should I switch?”; “But if you’re not going to quit using tobacco products, you should think about switching to Camel Snus.”* (Emphasis added throughout.) Therefore, a question was included to assess whether respondents understood that smokers’ health risks are reduced only if they quit smoking completely and use Camel Snus *instead of* cigarettes. Respondents were asked what action was needed in order for smokers to receive a health benefit from using Camel Snus, and two response options were provided: 1) stop smoking completely and use Camel Snus instead; and 2) continue to smoke, but use Camel Snus as well (Question 1a2 on the survey).

More than three-quarters (78%; 76.5%-79.5%) of all respondents indicated that smokers should “stop smoking completely and use Camel Snus instead” in order to receive a health benefit, while very few respondents indicated that Camel Snus should be used while continuing to smoke (4%; 3.9%-4.7%). A total of 18% (16.6%-19.4%) were unsure of the correct response to this question.

Subgroups of interest

Comprehension of the message about complete switching is particularly important for current tobacco users and potential quitters, who must understand that completely stopping smoking is required to receive a health benefit when using Camel Snus. Among current tobacco users, 77% (74.2%-79.8%) indicated that smokers should switch completely to Camel Snus; very few indicated that Camel Snus should be used while continuing to smoke (8%; 6.1%-9.9%); and 15% (12.7%-17.3%) were unsure. Among potential quitters, 79% (73.3%-84.7%) indicated that smokers should switch completely to Camel Snus; 10% (5.5%-14.5%) indicated that Camel Snus should be used while continuing to smoke; and 12% (8.0%-16.0%) were unsure of the correct response.

Across the other subgroups, only small percentages indicated that Camel Snus should be used while continuing to smoke (from a low of 2% for former tobacco users to a high of 10% for potential quitters). Those with limited health literacy were least likely to say that complete switching to Camel Snus was necessary (62%; 59.0%-65.0%) and most likely to say they did not know the answer (31%; 28.2%-33.8%); in this subgroup, very few indicated that Camel Snus should be used while continuing to smoke (7%; 5.5%-8.5%) (for detailed results across the different subgroups, see [Appendix A, Table 2](#) in Camel SNUS Modified Risk Messaging: Comprehension and Perceptions among Tobacco Users and Non-Users – Second Execution of Consumer Testing – Amended Final Report).

6.2.5.2.10.2 Respondents’ Understanding of the Proposed Advertising Emphasizing that Quitting Smoking is the Best Choice

For smokers concerned about the health risks of smoking, it is important that they understand that Camel Snus reduces some health risks compared to cigarette smoking, but quitting smoking is the best way to eliminate those risks. Understanding of this message aims to mitigate the possibility that smokers who might otherwise quit might adopt Camel Snus instead of quitting tobacco completely. Accordingly, the proposed advertisement indicated quitting as the best choice: *“If you’re a smoker concerned about the health risks from smoking, the best choice is to quit.”* (Italics added.) To assess understanding of this concept, respondents were asked whether “Quitting is the best choice for a smoker who is concerned about health risks from smoking” (yes/no/don’t know response options; Question 1a on the survey).

A strong majority of all respondents (87%; 85.7%-88.3%) correctly understood this message, with small proportions indicating the wrong answer (7%; 6.1%-7.9%) or being unsure of the correct answer (6%; 5.1%-6.9%).

Subgroups of interest

There was also excellent comprehension of the “best choice is to quit” message among the subgroups for whom this message is most relevant – 89% (86.9%-91.1%) of current tobacco users, 93% (91.5%-94.5%) of former tobacco users, and 91% (86.9%-95.1%) of potential quitters indicated that quitting is the best choice for a smoker concerned about the health risks from

smoking. Across the subgroups, those with limited health literacy had the lowest proportion of correct responses for this particular question (76%; 73.3%-78.7%), but still showed good comprehension (for the full results across the subgroups, see [Table 8](#) and [Appendix A, Table 1](#) in Camel SNUS Modified Risk Messaging: Comprehension and Perceptions among Tobacco Users and Non-Users – Second Execution of Consumer Testing – Amended Final Report).

6.2.5.2.10.3 Respondents’ Understanding of the Message that Former and Never Users of Tobacco Products Should Not Use Camel Snus

The proposed advertisement indicated that Camel Snus should not be used by non-tobacco users (both never and former users): “*Adults who do not use or who have quit using tobacco products should not start.*” To ensure respondents understood that Camel Snus should not be used by non-tobacco users, they were asked “Should adults who do not use or who have quit using tobacco products start using Camel Snus?” (yes/no/don’t know response options; Question 1a on the survey).

This message was correctly understood by 83% (81.6%-84.4%) of respondents overall; a small percentage (6%; 5.2%-6.8%) provided the incorrect response (yes); and 11% (9.8%-12.2%) were unsure of the correct response even though this question mirrored the statement in the proposed advertisement.

Subgroups of interest

This message is particularly important for former tobacco users and never tobacco users, who should not start using any tobacco product, including Camel Snus. The message that Camel Snus should not be used by those who don’t use tobacco products was well understood by former tobacco users (88%; 86.1%-89.9%) and never tobacco users (83%; 80.8%-85.2%). In the former and never tobacco user subgroups, those unsure of the correct response were 8% (6.3%-9.7%) and 13% (11.1%-14.9%), respectively. Among those with limited health literacy, 72% (69.2%-74.8%) answered correctly, but 19% (16.6%-21.4%) were unsure of the correct response (for the full results across the subgroups, see [Table 8](#) and [Appendix A, Table 1](#) in Camel SNUS Modified Risk Messaging: Comprehension and Perceptions among Tobacco Users and Non-Users – Second Execution of Consumer Testing – Amended Final Report).

6.2.5.3 Conclusions

The “Camel SNUS Modified Risk Messaging: Comprehension and Perceptions among Tobacco Users and Non-Users – Second Execution of Consumer Testing” study was conducted in accordance with the FDA’s MRTPA Draft Guidance to evaluate the effects of the proposed modified risk advertising for Camel Snus on current tobacco users’ and non-users’ understanding and perceptions. Overall, the results of this study suggest good comprehension of the proposed modified risk advertising for Camel Snus, and little indication that respondents were misled by the messaging. Across the different questions posed to respondents, although less than perfect comprehension was demonstrated, strong majorities showed understanding of the absolute and relative risks of Camel Snus in the context of the following messaging:

- Camel Snus poses less risk than cigarette smoking for particular diseases (*i.e.*, lung cancer, respiratory disease, heart disease, and oral cancer).
- However, Camel Snus is not completely without risk.
- Camel Snus is not a safer alternative than NRTs that are used to quit tobacco.
- Camel Snus is not a safer alternative than quitting tobacco entirely.
- Camel Snus is addictive.
- Current smokers who switch completely from cigarettes to Camel Snus can greatly reduce their health risks.
- Quitting all tobacco products is the best choice for current tobacco users concerned about health risks.
- Former and never users of tobacco products should not use Camel Snus.

A key message conveyed in the tested proposed advertisement was that Camel Snus reduces the health risks of lung cancer, respiratory disease, heart disease, and oral cancer. This message was understood by a majority of respondents – about two-thirds indicated that Camel Snus carried less risk (but still some risk) for the first two conditions, and average ratings of risk were lower for Camel Snus relative to cigarette smoking. Thus, the advertisement generally conveyed the concept of reduced risk for Camel Snus.

Importantly, respondents understood that Camel Snus was not completely safe and still carried some risk. Less than 10% considered Camel Snus to be without risk for the diseases assessed, and perceived risk ratings consistently averaged above 4 on a 7-point risk scale (where 1 meant no risk), implying considerable risk. Thus, respondents viewing the proposed advertisement did not over-extend the messaging to conclude that Camel Snus was completely safe. This is an important finding, as it supports the idea that smokers may benefit from switching from cigarette smoking to Camel Snus, but that non-tobacco-users should not adopt use of Camel Snus, as this may subject them to risk.

Similarly, respondents did not over-generalize the stated risk reduction to general health, rating the risk of Camel Snus to "generally poor health" at 5.7 on the 7-point risk scale, where 1 represented no risk. In other words, respondents considered that use of Camel Snus was a considerable risk to health, beyond the specific diseases mentioned. The advertisement did not address the effect of Camel Snus on any other disease, leading 83% to conclude that it either did not reduce the risk of other diseases (35%) or that they did not know its effect on other diseases (48%). Respondents also generally understood that Camel Snus is addictive. Thus, the modified risk messaging in the proposed advertisement led to respondent beliefs that were typically neither overstated nor over-generalized.

Indeed, respondents' assumptions about the expected reduction in risk from switching from cigarette smoking to Camel Snus appeared to be quite modest, likely understating the actual risk reduction, particularly for lung cancer and respiratory diseases. Further, given the explicit statements in the proposed advertisement that Camel Snus reduced the risk of the four diseases listed, it was striking that substantial minorities of respondents stated that Camel Snus carried the *same* risk as continuing to smoke: 37% believed this for oral cancer, and 20-25% for lung cancer, respiratory disease, and heart disease. Also, as suggested by these estimates, respondents made distinctions among the diseases mentioned in the proposed advertisements, even though the proposed advertisement noted risk reduction for each of them without distinguishing among them or providing comparative or quantitative information. This strongly suggests that the respondents formulated their responses not just based on what they read and understood from the advertisement itself, but additionally were influenced by pre-existing beliefs and intuitions. Multiple findings indicate that many Americans believe that smokeless tobacco is as dangerous or more dangerous than smoking (Fong *et al.* 2016; Kaufman *et al.* 2014; Kiviniemi and Kozlowski 2015; Liu *et al.* 2015; O'Connor *et al.* 2005a; Regan *et al.* 2012; Smith *et al.* 2007; Wray *et al.* 2012), and particularly believe that since smokeless tobacco comes in contact with the mouth, but, unlike smoking, is not inhaled, that its effects would be greater on oral cancer than on diseases of the respiratory system (lung cancer and respiratory disease) (Choi *et al.* 2012; Pepper *et al.* 2015).

Thus, the opinions provided by respondents after exposure to the advertisement must be seen in the context of the prevailing public misperception that smokeless tobacco, including snus, is at least as harmful as smoking (Fong *et al.* 2016; Kaufman *et al.* 2014; Kiviniemi and Kozlowski 2015; Liu *et al.* 2015; Regan *et al.* 2012; Wray *et al.* 2012), especially for oral cancer (Choi *et al.* 2012; Pepper *et al.* 2015). Given this prevailing view, and the skepticism with which reduced risk information is received (Borland *et al.* 2012), it is understandable that some respondents continued to believe that Camel Snus was as harmful as smoking. In practice, modified risk messaging may need repetition and endorsement from multiple credible sources to become more persuasive and believable to consumers, so as to change their beliefs and to support changes in tobacco use behavior.

Respondents not only did not overstate the risk reduction attributable to Camel Snus, but they also did not over-generalize it to all other smokeless products. The risk of other smokeless tobacco products was rated higher than that of Camel Snus for each of the four diseases mentioned in the advertisement. Nor did most respondents believe that Camel Snus was as safe as nicotine replacement medications, though this comparison was less well understood than the comparison to cigarette smoking. This is not surprising in light of shared misperceptions about the harms of nicotine even in FDA-approved medications (Borland *et al.* 2011; Ferguson *et al.* 2011; Smith *et al.* 2007), and the widespread belief that nicotine is a primary harmful ingredient in tobacco and NRT products (Bansal *et al.* 2004; Ferguson *et al.* 2011; Mooney *et al.* 2006). Mitigating public misperceptions about Camel Snus may benefit from addressing broader misconceptions about nicotine and its role in smoking-related harms (Borland *et al.* 2011; Borland *et al.* 2012; Ferguson *et al.* 2011; Regan *et al.* 2012).

6.2.5.3.1 Subgroups

Certain messages in the proposed advertisement are of special relevance to particular subgroups. Accordingly, comprehension and perceptions were also evaluated in subgroups of interest. The results showed good comprehension for most of these message-by-subgroup pairings. For example, a strong majority of current tobacco users (89%) understood the message that quitting smoking is the best option for smokers concerned about health risks. This suggests that messages about reduced risk would not deter smokers from quitting, and that using Camel Snus would not be seen as an adequate substitute for quitting. Over three-quarters of current tobacco users (77%) understood that smokers' health risks are reduced only if they stop smoking completely and use Camel Snus instead of cigarettes. Few (8%) said that Camel Snus would confer a health benefit if used while smoking. Thus, respondents generally understood that the benefit of Camel Snus would come from substituting Camel Snus for smoking, and that the optimal course was to stop smoking without the use of Camel Snus.

Further, current tobacco users who were potential quitters had excellent understanding (91%) of the message that quitting is the best choice for smokers, suggesting that the offer of Camel Snus would not lead them to think of Camel Snus as an alternative to quitting, and thus deter them from quitting. Similarly, subgroups that were not current tobacco users – former tobacco users and never users – well understood that non-users should not use Camel Snus (88% and 83%, respectively), suggesting that the messaging would not attract initiation among these non-user groups.

The study also evaluated comprehension and perception among individuals with limited health literacy.

Studies have consistently demonstrated that limited health literacy is associated with lower comprehension and understanding of consumer communications including prescription and over-the-counter drug labels (Davis *et al.* 2006; Raymond *et al.* 2002; Shiffman *et al.* 2011; Wolf *et al.* 2006) and FDA risk communications (McCormack *et al.* 2016). Consistent with this, respondents with limited health literacy typically showed less understanding of the messages conveyed by the proposed advertisement, and were consistently more likely than any other subgroup to answer "don't know/not sure" when such options were available. The advertisement text included simple, direct wording, and used devices such as bullet points and white space, that are recommended for effective communication across the spectrum of health literacy (CCD 2009; Plain Language Action and Information Network, 2011). The proposed advertisement aims to communicate multiple messages, which can complicate communication, particularly on a single, brief exposure. It may be that repeated and prolonged exposure, or expression of the messages in different ways from different sources, may help communicate the messages to individuals with limited health literacy. In any case, even those with limited health literacy showed reasonable comprehension of key messages, notably *not* being led to think that use of Camel Snus carries no risk, that non-smokers should use Camel Snus, that Camel Snus is not addictive, or that smokers should simply add use of Camel Snus to their smoking. The results suggest that even individuals with limited

health literacy would not be put at risk by the proposed advertisement with the modified risk messaging.

Comprehension among ethnic minority respondents was somewhat lower overall than for Caucasian respondents. This may be because of the association between health literacy and minority status. Studies have shown that racial and ethnic minorities, particularly African Americans and Hispanics, have a higher prevalence of limited health literacy (IOM 2004; Kutner *et al.* 2006; Rudd 2007).

6.2.5.3.2 Limitations and Strengths

Like any study, this study had limitations. The sample was drawn from an opt-in online panel, and thus may not be fully representative of the U.S. population, not all of whom have internet access or join online panels. However, strong majorities of Americans are now online (Perrin and Duggan 2015), and online panels can produce reasonable estimates (Farrell and Petersen 2010). Moreover, the sample was diverse, and was recruited and weighted to represent the demographics of the U.S. population.

The proposed Camel Snus advertisement is intended to be displayed in multiple media, but in this study the advertisement was evaluated via an online, on-screen display in a research context. However, such methods are often used to evaluate communications (Sullivan *et al.* 2015), and there is little reason to think the results are not generalizable to other media. The study measured the effects of a single exposure of the proposed modified risk advertising for Camel Snus during the course of a study, as opposed to the effects of multiple exposures over time in the real world in the context of advertising. It is possible that repeated exposure over time to the modified risk advertising would lead to improved comprehension and understanding of the absolute and relative health risks of Camel Snus and cigarette smoking (Borland *et al.* 2012). Nonetheless, the results from this study indicate good comprehension of the proposed modified risk advertising for Camel Snus. The advertisement communicated a great deal of presumably new information about Camel Snus and its risk reduction potential relative to cigarette smoking.

Importantly, some of the information in the proposed advertisement was likely at odds with respondents' pre-existing beliefs, as research consistently shows that people believe that smokeless tobacco products are at least as hazardous as cigarettes (Fong *et al.* 2016; Kaufman *et al.* 2014; Kiviniemi and Kozlowski 2015; Liu *et al.* 2015; Regan *et al.* 2012; Wray *et al.* 2012). That respondents applied their own beliefs, and not just their understanding of the advertisement, was evident in the pattern of responses, particularly the differentiation of oral cancer risk compared to other risks (*see above*). Thus, some information may have been understood, but not believed (Borland *et al.* 2012). The fact that the source of the information was a tobacco company may have made the information less credible, as tobacco companies now rank among the least credible information sources (Byrne *et al.* 2012; Harris Interactive 2013). Multiple exposures to relevant messages, and support of messages from multiple credible sources, may help overcome people's current beliefs and misperceptions about smokeless tobacco and snus. Finally, the study itself was long and may have led to respondent fatigue.

The study also had considerable strengths. The sample was large, diverse, and sampled and weighted to match the demographics of U.S. adults. It included a broad range of demographics, including a substantial representation of individuals with limited health literacy. The assessment covered a broad range of messages identified by FDA in its Draft Guidance on MRTP applications, and thus addresses the issues of concern for modified risk messaging. The study sampled current, former, and never users of tobacco products, and also analyzed responses from important subgroups based on demographics or tobacco use history. Survey questions and algorithms used to characterize subgroups were drawn from well-established norms in the published literature. Questions about relative risk of Camel Snus were asked in two different ways, and generated consistent, convergent results.

6.2.5.4 Summary – Execution 2

This study assessed adults' responses to proposed Camel Snus modified risk advertising that carried a risk reduction message, and also conveyed important messages aimed to mitigate potential unintended consequences of modified risk messaging. The results showed that individuals exposed to such messages understood that Camel Snus carries less risk than cigarette smoking, but still carries considerable risk and is not completely safe. They understood that Camel Snus is addictive, that quitting smoking is the best choice, and that persons who do not already use tobacco should not use Camel Snus. In short, the proposed advertising was successful in communicating reduced risk while avoiding over-generalization of the risk messaging and mitigating any potential for the messaging to deter quitting or promote initiation. In sum, the proposed advertising was understood.

6.2.6 Camel SNUS Modified Risk Messaging: Comprehension and Perceptions among Tobacco Users and Non-Users – Third Execution of Consumer Testing

6.2.6.1 Study Methods

Sample

A study was conducted with a sample of 4,906 U.S. adults who, based on age (typically 18+) were legally eligible to purchase tobacco in their state of residence. The sample was drawn randomly from the Research Now online panel of approximately three million individuals in the U.S. Quota sampling was done to obtain approximately 1,500 respondents each in three tobacco user groups of interest (current tobacco users, former tobacco users, and never tobacco users, described below). Quota sampling was also used to maximize representativeness with respect to gender, age, race/ethnicity, education, and geographic region. Sampling was done to ensure a minimum of 100 respondents in other subgroups of interest, including those with limited health literacy, ethnic minorities, young adults ages 18-24, and white males (who are the primary users of smokeless tobacco [[USDHHS 2014](#)]). Young adults ages 18-24 were analyzed as a subgroup, as a proxy for those under legal purchase age.

The three tobacco user groups of interest were as follows:

1. Current tobacco users (n=1,317), defined as those who met historical usage thresholds for at least one tobacco product (*i.e.*, smoked at least 100 cigarettes in lifetime [[Bondy et al. 2009](#)], or ever fairly regularly used any other tobacco product), and used tobacco “every day” or “some days” at the time of the study;
2. Former tobacco users (n=1,522), defined as those who met historical usage thresholds for at least one tobacco product, but did not use tobacco at all at the time of the study; and
3. Never tobacco users (n=1,503), defined as those who reported having never used tobacco, even once or twice.

An additional sample of experimental tobacco users (n=564) was surveyed to capture those who have used tobacco products but have not become established users. The final sample (n=4,906) was weighted to match the U.S. population in terms of gender, age, race/ethnicity, education, and geographic region. A detailed description of the sampling plan and weighting is available in the study protocol ([Protocol Identifier: RO-BR-2015-03 Camel Snus Modified Risk Messaging: Comprehension and Perceptions among Tobacco Users and Non-Users – Third Execution of Consumer Testing](#)) and the final study report ([Camel SNUS Modified Risk Messaging: Comprehension and Perceptions among Tobacco Users and Non-Users – Third Execution of Consumer Testing – Amended Final Report](#)), respectively.

Additional Subgroups

Consistent with the tobacco literature ([CDC 1994](#)), established tobacco users (current and former users) were identified based on having achieved a sufficiently high level of use to qualify as established users. For example, based on the literature ([Bondy et al. 2009](#)), those who have not smoked at least 100 cigarettes in their lifetime have not become established smokers. These individuals, however, could eventually progress to current smoking. To capture those who have used tobacco products but have not become established users, an additional sample of 564 experimental tobacco users (referred to as “experimenters”) was surveyed. For the purposes of this study, experimenters were defined as those who reported (a) having ever used a tobacco product, even once or twice; (b) not meeting historical usage thresholds for any tobacco product to be considered a “regular” user; and (c) use of tobacco “every day” or “some days” at the time of the study.

In addition, “potential quitters” (n=307) were identified among current tobacco users. For the purposes of this study, potential quitters were defined as those who (a) reported having stopped use of tobacco for one day or longer in the past 12 months in an effort to quit tobacco completely; (b) indicated they wanted to quit using tobacco “somewhat” or “a lot”; (c) rated the likelihood of trying to quit tobacco in the next 30 days as “somewhat” or “very” likely; and (d) rated the likelihood of being successful in quitting tobacco as “somewhat likely” or “very likely” if a quit attempt was made. Individuals who meet these criteria are considered more likely to quit tobacco use ([Sciamanna et al. 2000](#)) and are an important subgroup in which to examine the effects of the proposed modified risk advertising for Camel Snus.

Procedures

The study was conducted June 16, 2015 to July 21, 2015. Respondents were screened for demographics and use of tobacco products (for the screener, see [Protocol Identifier: RO-BR-2015-03 Camel Snus Modified Risk Messaging: Comprehension and Perceptions among Tobacco Users and Non-Users – Third Execution of Consumer Testing](#)). Qualified respondents were shown the proposed Camel Snus modified risk advertisement that included proposed modified risk messaging. The advertisement consisted of three separate color images that appeared one above the other on the same screen. The bottom fifth of each image included one of four government-mandated warning label statements, randomly rotated for study respondents (for the advertisements viewed by respondents, see [Protocol Identifier: RO-BR-2015-03 Camel Snus Modified Risk Messaging: Comprehension and Perceptions among Tobacco Users and Non-Users – Third Execution of Consumer Testing](#)). The proposed modified risk advertising included the following statements (verbatim):

- Smokers who switch completely from cigarettes to Camel Snus can greatly reduce their risk of lung cancer and respiratory disease.
- No smoke = less risk.
- Scientific studies have shown that Camel Snus contains less of the harmful chemicals than cigarette smoke.
- Switching to snus means less risk for you and those around you.
- Switch completely from cigarettes to Camel Snus.
- No tobacco product is safe.
- 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.
- But if you're not going to quit using tobacco products, you should think about switching to Camel Snus.

Following exposure to the advertisement, respondents were asked questions to assess their comprehension and perceptions of the absolute health risks of Camel Snus, as well as health risks relative to cigarette smoking, cessation aids, and quitting all tobacco use (for the survey, see [Protocol Identifier: RO-BR-2015-03 Camel Snus Modified Risk Messaging: Comprehension and Perceptions among Tobacco Users and Non-Users – Third Execution of Consumer Testing](#)). Respondents could view the advertisement and refer to it at any time during the study. The survey questions appeared on the same screen directly below the advertisement, allowing respondents to scroll between the questions and the advertisement as desired. Questions posed to respondents were adapted from published studies that addressed health risk beliefs and risk perceptions of different types of tobacco products (e.g., [Haddock et al. 2004](#); [O'Connor et al.](#)

2005a; Peiper *et al.* 2010). At the end of the study, a health literacy test (*i.e.*, Newest Vital Sign, NVS) (Weiss *et al.* 2005) was completed by all respondents. This test assesses literacy based on respondents' ability to interpret an FDA food label.

Analysis

For the sample as a whole, and for various subgroups, responses to questions addressing the major communications objectives were summarized descriptively by means and 95% confidence intervals (for numerical ratings) or percentages and 95% confidence intervals (for categorical variables). No tests of statistical significance were conducted. For questions about comparative risks of Camel Snus and cigarette smoking, the proportion of respondents indicating that Camel Snus had at least some risk was computed by combining those who stated that Camel Snus has the same risk as smoking and those who stated that Camel Snus has less risk than smoking but still has some risk. All data were averaged across the sub-samples that each saw one of four randomly-rotated government-mandated smokeless tobacco warning label statements.

6.2.6.2 Study Results

The results of the “Camel SNUS Modified Risk Messaging: Comprehension and Perceptions among Tobacco Users and Non-Users – Third Execution of Consumer Testing” study are summarized below. The results are presented for the full sample overall, as well as the particular subgroups for which a specific modified risk message is most relevant (*e.g.*, messaging about quitting tobacco use for current tobacco users, messaging about the health risks of Camel Snus relative to quitting all tobacco use for current tobacco users and potential quitters). In addition, results for certain populations, including minorities and those with limited health literacy, are reported where there are material differences.

The final study report for this study is submitted with this Application and includes the complete tabulation of study results and findings for each of the subgroups of interest (*i.e.*, current tobacco users, former tobacco users, never tobacco users, experimenters, potential quitters, those with limited health literacy, minorities, young adults ages 18-24, and white males) ([Camel SNUS Modified Risk Messaging: Comprehension and Perceptions among Tobacco Users and Non-Users – Third Execution of Consumer Testing – Amended Final Report](#)). All results for each subgroup are not repeated in this summary; however, ranges across groups, and particular subgroup results are discussed when particularly relevant or where there are material differences.

6.2.6.2.1 Demographics

Among the 4,906 respondents, 27% (n=1,317) were current tobacco users, 31% (n=1,522) were former tobacco users, and 31% (n=1,503) were never tobacco users, and 11% (n=564) were

experimenters. Among the current tobacco users, 74% were current cigarette smokers⁷ (56% every day; 18% some days), 6% were current snus users, and 12% used other forms of smokeless tobacco. A total of 9% were current users of more than one tobacco product. Respondents were 18 and older, including 16% aged 18-30, 36% aged 31-50, and 48% aged 51 and older. The sample was 50% female; 30% had a high school education, 34% completed some college, and 36% had a bachelor's or advanced degree. The majority of the sample was non-Hispanic Caucasian (78%), 8% were of Hispanic, Latino, or Spanish origin, 8% were non-Hispanic African American, and 7% were non-Hispanic Asian or other race. In terms of geographic distribution, 34% were from the South, 22% from the West, 23% from the Midwest, and 20% from the Northeast. The weighted demographic profile of the full sample was comparable to the U.S. population overall (for the demographic profile of the sample by tobacco user group, see [Table 2](#) [unweighted data] and [Table 6](#) [weighted data] in Camel SNUS Modified Risk Messaging: Comprehension and Perceptions among Tobacco Users and Non-Users – Third Execution of Consumer Testing – Amended Final Report). A total of 35% of the overall sample was assessed to have limited health literacy, based on the NVS test⁸.

6.2.6.2.2 Respondents' beliefs about the health risks of Camel Snus relative to cigarette smoking, and Camel Snus absolute risks

The FDA MRTPA Draft Guidance indicates that a critical issue to address is consumers' beliefs about the health risks of the MRTP relative to cigarette smoking. Ideally, consumers should understand that the MRTP (Camel Snus) carries lower risk than cigarette smoking for certain diseases, but they should not view the MRTP (Camel Snus) as being completely safe or free of risk.

Respondents' understanding of the risks of Camel Snus relative to smoking was evaluated in two ways: through comparison of quantitative ratings of risk for each product, and by asking respondents to directly characterize qualitatively the risk of Camel Snus relative to smoking.

Quantitative ratings of risk

As one way to capture perceptions of risk, respondents were asked to rate (on a 7-point scale ranging from “no risk” to “substantial risk”) the impact of Camel Snus and cigarette smoking on the risk of developing the two diseases that were mentioned in the proposed advertisement (lung cancer and respiratory disease) (Questions 2a and 2c on the survey; [Protocol Identifier: RO-BR-](#)

⁷ Respondents were considered cigarette smokers if they smoked manufactured cigarettes. Only 0.6% (n=29) of respondents indicated smoking roll-your-own cigarettes; these were counted as tobacco users but not cigarette smokers.

⁸ Consistent with findings from other studies ([IOM 2004](#); [Kutner et al. 2006](#); [Rudd 2007](#)), there were substantial variations in assessed health literacy by ethnicity in this study, with African American (57%) and Hispanic (50%) respondents more likely to be assessed as having limited health literacy than fall into this assessed category compared to Caucasian (31%), Asian (40%), or other respondents (29%). Overall, 48% of minority (non-Caucasian) respondents scored as having limited health literacy. This likely affects comparisons of comprehension by ethnicity.

2015-03 Camel Snus Modified Risk Messaging: Comprehension and Perceptions among Tobacco Users and Non-Users – Third Execution of Consumer Testing).

Table 6.2.6-1 below summarizes respondents’ beliefs about the health risks associated with Camel Snus and cigarette smoking. Overall, mean risk ratings for Camel Snus for the diseases were always lower than those for cigarette smoking, demonstrating that respondents correctly understood that Camel Snus presents less risk than cigarette smoking.

At the same time, respondents also understood that Camel Snus nevertheless carried some risk, as is evident from the risk ratings they assigned to Camel Snus on the 1 to 7 scale (Table 6.2.6-1 below). Mean ratings for risk of lung cancer and respiratory disease with Camel Snus were 4.8 and 4.7, respectively. Importantly, all Camel Snus risk ratings fell above the midpoint of the 1-7 scale. For comparison, risk ratings for cigarette smoking were 6.6 for both lung cancer and respiratory disease. Therefore, respondents also understood that Camel Snus does pose *at least some risk* for each disease, and that risk is not zero (*i.e.*, no risk at all).

Table 6.2.6-1: Respondents’ (n=4,906) Beliefs about the Health Risks of Camel Snus, Cigarette Smoking, and Smokeless Tobacco

	Camel Snus	Cigarette Smoking	Smokeless Tobacco (other than Camel Snus)
Risk of developing lung cancer *	4.8** (4.74-4.86)	6.6 (6.56-6.64)	5.2 (5.14-5.26)
Risk of developing respiratory disease	4.7 (4.63-4.77)	6.6 (6.56-6.64)	5.1 (5.04-5.16)
Risk of developing heart disease	5.4 (5.34-5.46)	6.3 (6.26-6.34)	5.7 (5.65-5.75)
Risk of developing oral cancer	6.0 (5.95-6.05)	6.1 (6.05-6.15)	6.3 (6.25-6.35)

* Rated on a 7-point scale ranging from 1 (“no risk”) to 7 (“substantial risk”)

** Mean risk rating (95% confidence interval in parentheses)

Indeed, the numerical ratings give some insight into the degree of risk reduction that respondents assumed for Camel Snus compared to smoking. The mean ratings for cigarette smoking are quite high, near the top limit of the scale (designated as "substantial risk"). The estimates for Camel Snus were lower, but very modestly so⁹. Even for lung cancer and respiratory disease, respondents on average attributed very substantial risks to use of Camel Snus.

⁹ It is possible to calculate crude estimates of the relative reduction in risk from the 1-7 risk ratings made by respondents. The ratings were scaled such that 1 = "no risk." Subtracting 1 from the ratings thus sets 0 equal to "no risk," allowing crude computations of risk reduction implied by the ratings, and expressing the risk attributed to Camel Snus as a percentage of that attributed to smoking. On this basis, the respondents' ratings of Camel Snus versus smoking imply a 32% risk reduction for lung cancer, a 34% risk reduction for respiratory disease, a 17% reduction for risk of heart disease, and a 2% risk reduction for oral

Subgroups of interest

Consistent with the results for the full sample, across each of the subgroups (including limited health literacy and minority respondents) the mean risk ratings for Camel Snus for lung cancer and respiratory disease were always lower than those for cigarette smoking ([Appendix B, Tables 4 and 5](#) in *Camel SNUS Modified Risk Messaging: Comprehension and Perceptions among Tobacco Users and Non-Users – Third Execution of Consumer Testing – Amended Final Report*).

The mean risk ratings for all subgroups also indicated understanding that Camel Snus does carry some risk of each disease. Even the lowest mean risk rating assigned to any one disease (respiratory disease) reflected an expectation of significant risk across all subgroups (*e.g.*, current tobacco users [3.8; 95% confidence interval =3.67-3.93], former tobacco users [4.4; 4.30-4.50], never tobacco users [5.0; 4.90-5.10], experimenters [4.3; 4.07-4.53], and young adults ages 18-24 [4.4; 4.12-4.68]) (for detailed results for the subgroups, see [Appendix B, Tables 4 and 5](#) in *Camel SNUS Modified Risk Messaging: Comprehension and Perceptions among Tobacco Users and Non-Users – Third Execution of Consumer Testing – Amended Final Report*).

Qualitative characterization of risk

In another risk perception question, respondents were asked specifically to characterize what the advertisement communicated about the level of risk of using Camel Snus as (a) reduced relative to smoking, (b) similar to that of smoking, (c) having no risk at all, or (d) don't know/not sure response option. These judgments were made separately with respect to lung cancer and respiratory disease, the two diseases specifically mentioned in the advertisement (Question 1b on the survey).

[Table 6.2.6-2](#) below summarizes respondents' understanding of the risk reduction of Camel Snus compared to continued smoking. Respondents were very consistent in their responses across the two different disease risks specifically mentioned in the proposed advertisement.

About two-thirds indicated that compared to smoking, Camel Snus has less risk of lung cancer (62%) and respiratory disease (63%). Across both diseases, 9-10% of respondents indicated they did not know or were not sure what the risk of Camel Snus was relative to cigarette smoking. The basic risk reduction message was not understood, or not believed, by some respondents, such that 19% reported that Camel Snus poses the same risk of lung cancer and respiratory disease as cigarette smoking. Approximately 10% of respondents did not know or were not sure what the risk of Camel Snus was, whether on an absolute or relative basis.

Consistent with the quantitative ratings, few respondents believed that Camel Snus had no risk at all. This risk characterization was endorsed by 10% of respondents for each disease. Similarly,

cancer. These implied risk reductions are much more modest than those derived from expert consensus [[Levy et al. 2004](#); [Nutt et al. 2014](#)], which imply roughly 90% risk reduction.

81%-82% indicated that Camel Snus carries at least some risk for each disease. This suggests that respondents understood that Camel Snus is not risk-free and still poses some risk.

Table 6.2.6-2: Respondents’ (n=4,906) Understanding of the Health Risks of Camel Snus Relative to Continuing to Smoke

	Same risk as continuing to smoke	Less risk than continuing to smoke, but some risk	Net “some risk”	No risk at all	Don’t know / Not sure
Lung cancer risk	19% (17.5%-20.5%)	62% (60.3%-63.7%)	81% (79.6%-82.4%)	10% (9.0%-11.0%)	9% (7.9%-10.1%)
Respiratory disease risk	19% (17.5%-20.5%)	63% (61.3%-64.7%)	82% (80.6%-83.4%)	9% (8.0%-10.0%)	10% (8.9%-11.1%)

*95% confidence interval

Subgroups of interest

Among current tobacco users – a subgroup for whom the modified risk advertising is particularly relevant – at least 78% stated that Camel Snus is associated with some risk of lung cancer or respiratory disease, and 14% and 15%, respectively, stated that Camel Snus was associated with no risk (for detailed results for the subgroups, see [Appendix A, Table 3](#) in Camel SNUS Modified Risk Messaging: Comprehension and Perceptions among Tobacco Users and Non-Users – Third Execution of Consumer Testing – Amended Final Report). Similarly, among potential quitters – another subgroup for whom this message is highly relevant – at least 77% stated that Camel Snus is associated with some risk of each disease, while 16% reported no risk for lung cancer or respiratory disease, respectively.

As expected, those with limited health literacy demonstrated lower overall comprehension of or belief in the risk reduction messaging, relative to all other respondents. For both diseases, less than 50% of those with limited health literacy correctly indicated Camel Snus poses less risk than smoking, while 29% to 30% indicated equal risk for Camel Snus and smoking. However, consistent with the responses of all other respondents, less than 10% of limited health literacy respondents incorrectly indicated that the advertisement conveyed no risk at all with Camel Snus for either disease ([Appendix A, Table 3](#) in Camel SNUS Modified Risk Messaging: Comprehension and Perceptions among Tobacco Users and Non-Users – Third Execution of Consumer Testing – Amended Final Report), suggesting that this misperception was not prevalent even among those who may have had trouble understanding the messaging.

Among minority (*i.e.*, non-Caucasian) respondents, at least 82% stated that Camel Snus is associated with some risk of either disease. Only 8% (6.0%-10.0%) (for lung cancer) and 7% (5.2%-8.8%) (for respiratory disease) incorrectly indicated no risk at all, again suggesting understanding of this aspect of the message. In no subgroup examined did the percentage of respondents believing Camel Snus posed no risk at all exceed 16% (this was the highest percentage, among potential quitters, for risk of lung cancer and respiratory disease, respectively).

6.2.6.2.3 Perceptions of risk across the diseases mentioned in the proposed advertisement

The proposed advertisement mentioned reduced risk of lung cancer and respiratory disease, and there was no mention of heart disease or oral cancer. In their responses, respondents distinguished the risk of these respiratory/pulmonary conditions from the risk of heart disease and oral cancer. Respondents consistently rated the risk of oral cancer higher than that of the respiratory conditions – in quantitative ratings using the 1 to 7 scale (Table 6.2.6-2 above), the risk of oral cancer was rated at 6.0, whereas the risk of lung cancer was rated 4.8 and respiratory disease was rated 4.7. The risk of heart disease was intermediate at 5.4.

This pattern of beliefs about risk corresponds to that seen in recent qualitative research on the public's perceptions of snus (Choi *et al.* 2012), where respondents inferred oral cancer risk from the fact that oral tobacco products come into direct contact with the mouth. The results suggest that these intuitions, which likely pre-existed exposure to the proposed modified risk advertising, persisted after exposure to the modified risk messages. This further indicates that respondents did not over-generalize from the messaging about particular conditions (respiratory conditions) addressed in the proposed advertisement to others (heart disease and oral cancer).

Subgroups of interest

Each of the different subgroups rated the risk of oral cancer with Camel Snus higher than that of the respiratory conditions in the quantitative assessment of risk (Appendix B, Table 4 in Camel SNUS Modified Risk Messaging: Comprehension and Perceptions among Tobacco Users and Non-Users – Third Execution of Consumer Testing – Amended Final Report). The lowest mean risk rating for Camel Snus was always assigned to respiratory disease across all subgroups (mean ratings ranged from 3.8 to 5.0), but such ratings still reflect an understanding of some risk posed by Camel Snus.

6.2.6.2.4 Respondents' Understanding of Relative Risks for Diseases Not Mentioned in the Proposed Advertisement

It was conceivable that respondents might generalize the information provided in the proposed modified risk advertisement to apply to diseases not explicitly mentioned. This was assessed in two ways in the study. Respondents were specifically asked whether Camel Snus reduced the risk of diseases not mentioned in the advertisement. Also relevant to this were respondents' quantitative ratings of the risk of heart disease and oral cancer (diseases not mentioned in the advertisement) due to smoking, use of Camel Snus, and use of other smokeless tobacco.

Qualitative characterization of risk

To assess respondents' judgments about the generalization of risk reduction, a question was posed regarding the risk reduction potential of Camel Snus for other diseases *not mentioned in the advertisement* (Question 2g on the survey).

Across all respondents, 16% (14.7%-17.3%) believed that “Camel Snus reduces the risk of other smoking-related diseases that are not discussed in the ad” (yes/no/don’t know response options); 37% (35.3%-38.7%) indicated ‘no’, but most (48%; 46.2%-49.8%) were understandably unsure. Although some generalization is likely reasonable, the data suggest that the messaging did not lead respondents to make sweeping generalizations or draw strong conclusions about diseases not explicitly mentioned in the advertisement ([Table 9](#) in Camel SNUS Modified Risk Messaging: Comprehension and Perceptions among Tobacco Users and Non-Users – Third Execution of Consumer Testing – Amended Final Report).

Subgroups of interest

The results for the diseases “not mentioned in the advertisement” question for the different subgroups were similar to those for all respondents (Appendix B, Table 7 in Camel SNUS Modified Risk Messaging: Comprehension and Perceptions among Tobacco Users and Non-Users – Third Execution of Consumer Testing – Amended Final Report). Those who reported that Camel Snus reduced the risk of other diseases not mentioned in the advertisement ranged from a low of 14% for never tobacco users to a high of 31% for potential quitters. In addition, 27-41% in each subgroup indicated ‘no’, and 40-52% were unsure. Of interest, among all of the different subgroups, those most likely to say that Camel Snus did not reduce the risk of diseases not mentioned in the advertisement included never tobacco users (41%; 38.2%-43.8%), those with limited health literacy (41%; 37.9%-44.1%), and minority respondents (41%; 37.3%-44.7%).

Quantitative ratings of risk

Respondents were asked to rate (on a 7-point scale ranging from “no risk” to “substantial risk”) the impact of Camel Snus and cigarette smoking on the risk of developing heart disease and oral cancer, two diseases that were not mentioned in the advertisement (Questions 2b and 2d on the survey).

[Table 6.2.6-3](#) below summarizes respondents’ beliefs about the health risks associated with Camel Snus, cigarette smoking, and smokeless tobacco other than Camel Snus. Respondents rated the risk of oral cancer due to use of Camel Snus nearly as high as that of smoking (6.0 vs 6.1). There was more of a gap between Camel Snus and smoking in their ratings of heart disease, where respondents rated Camel Snus at 5.4, compared to 6.3 for smoking. Other smokeless tobacco products were rated as higher risk than Camel Snus. As heart disease and oral cancer were not mentioned in the advertisement, it is likely that respondents used their intuitive understanding of disease causation to form these impressions. For example, studies show that people assume that smokeless tobacco is likely to cause oral cancer, because of the product’s prolonged contact with the mouth ([Choi et al. 2012](#); [Pepper et al. 2015](#)).

Table 6.2.6-3: Respondents’ (n=4,906) Beliefs about the Health Risks of Camel Snus, Cigarette Smoking, and Smokeless Tobacco

	Camel Snus	Cigarette Smoking	Smokeless Tobacco (other than Camel Snus)
Risk of developing heart disease	5.4 (5.34-5.46)	6.3 (6.26-6.34)	5.7 (5.65-5.75)
Risk of developing oral cancer	6.0 (5.95-6.05)	6.1 (6.05-6.15)	6.3 (6.25-6.35)

* Rated on a 7-point scale ranging from 1 (“no risk”) to 7 (“substantial risk”)

** Mean risk rating (95% confidence interval in parentheses)

Subgroups of interest

Across each of the subgroups (including limited health literacy and minority respondents), the mean risk ratings for oral cancer due to use of Camel Snus were nearly as high, or equal to that, of cigarette smoking; and in the subgroup of white males, the risk rating for Camel Snus for oral cancer (6.0) was slightly higher than that of cigarette smoking (5.9). There was more of a gap between Camel Snus and smoking for each of the subgroups’ risk ratings of heart disease – the mean risk ratings for Camel Snus were always lower than those for cigarette smoking. Across each of the subgroups, other smokeless tobacco products were rated as higher risk than Camel Snus for both oral cancer and heart disease, consistent with the results for the full sample ([Appendix B, Tables 4, 5, and 6](#) in *Camel SNUS Modified Risk Messaging: Comprehension and Perceptions among Tobacco Users and Non-Users – Third Execution of Consumer Testing – Amended Final Report*).

6.2.6.2.5 Respondents’ Beliefs about the Risk of Developing Generally Poorer Health

Respondents were also asked to rate the impact of Camel Snus, cigarette smoking, and smokeless tobacco use (other than Camel Snus) on risk of “developing generally poorer health”, using the same scale used to rate Camel Snus and cigarette smoking (a 7-point scale ranging from “no risk” to “substantial risk”; Question 2e on the survey). The proposed advertisement did not include any specific reference to overall health, but mentioned two serious diseases (lung cancer and respiratory disease) that might be taken as relevant to overall health status.

[Table 6.2.6-4](#) below shows respondents’ mean risk ratings for the risk of developing poorer health for Camel Snus and cigarette smoking. The ratings show that the risk for Camel Snus (5.8) is rated lower than that of cigarette smoking (6.5). The risk rating assigned to Camel Snus for poorer health (5.8) was higher than that assigned to it for risk of lung cancer (4.8) or respiratory disease (4.7), the diseases mentioned in the advertisement ([Table 6.2.6-1](#) above). The ratings suggest that respondents believed that Camel Snus carries considerable risk to overall health, though not as high a risk as smoking does.

Table 6.2.6-4: Respondents’ (n=4,906) Beliefs about the Risk of Developing Poorer Health for Camel Snus, Cigarette Smoking, and Smokeless Tobacco

	Camel Snus	Cigarette Smoking	Smokeless Tobacco (other than Camel Snus)
Risk of developing generally poorer health	5.8 (5.74-5.86)	6.5 (6.46-6.54)	6.1 (6.05-6.15)

* Rated on a 7-point scale ranging from 1 (“no risk”) to 7 (“substantial risk”)

** Mean risk rating (95% confidence interval in parentheses)

Subgroups of interest

The results across the subgroups for ratings of risk of developing generally poorer health were consistent with those for the full sample – for each subgroup, the mean risk ratings for Camel Snus (range = 5.2-6.0) were always lower than those for cigarette smoking (range = 6.2-6.7) (Appendix B, Tables 4 and 5 in Camel SNUS Modified Risk Messaging: Comprehension and Perceptions among Tobacco Users and Non-Users – Third Execution of Consumer Testing – Amended Final Report). In addition, across each of the different subgroups, the risk rating assigned to Camel Snus for generally poorer health was higher than that assigned to it for risk of lung cancer and respiratory disease. In other words, respondents expected that the effects of Camel Snus on their general health would be more adverse than its effects on the diseases for which the advertisement claimed reduced risk.

6.2.6.2.6 Respondents’ Beliefs about the Health Risks of Camel Snus Relative to Smokeless Tobacco

In addition to assessing comprehension of how the risk of Camel Snus compares with cigarette smoking, FDA’s MRTPA Draft Guidance recommends that applicants also assess perceptions of risk for the MRTP compared to other tobacco products in the same class. Accordingly, respondents were also asked to rate the impact of smokeless tobacco use (other than Camel Snus) on the risk of developing lung cancer and respiratory disease, using the same scale used to rate Camel Snus and cigarette smoking (a 7-point scale ranging from “no risk” to “substantial risk”; Questions 2a and 2c on the survey).

Table 6.2.6-1 above summarizes respondents’ ratings of the health risks associated with Camel Snus and smokeless tobacco use. The ratings show that the risks of other smokeless tobacco products are rated higher than that of Camel Snus for lung cancer and respiratory disease, with the difference between Camel Snus and other smokeless tobacco products being consistently smaller than that between Camel Snus and cigarette smoking. Mean risk ratings for cigarette smoking were always the highest. These results suggest good comprehension of the modified risk advertising – the majority of respondents indicated that other smokeless tobacco products pose more risk of lung cancer and respiratory disease than Camel Snus. In a similar vein, as seen in Table 6.2.6-4, the risk of other smokeless tobacco on "generally poorer health" was rated higher than the risk of Camel Snus (6.1 vs. 5.8), but lower than the risk of cigarette smoking (6.5 vs. 6.1).

This suggests that respondents did not generalize the modified risk advertising to apply to all smokeless tobacco products.

Subgroups of interest

Consistent with the results for the full sample, across each of the subgroups (including those with limited health literacy and minority respondents) the mean risk ratings for other smokeless tobacco for lung cancer and respiratory disease were always higher than those for Camel Snus ([Appendix B, Tables 4 and 6](#) in *Camel SNUS Modified Risk Messaging: Comprehension and Perceptions among Tobacco Users and Non-Users – Third Execution of Consumer Testing – Amended Final Report*). This suggests all subgroups perceived that other smokeless tobacco poses more risk than Camel Snus, and that the modified risk advertising was not generalized to all smokeless tobacco.

6.2.6.2.7 Respondents’ Beliefs about the Health Risks of Camel Snus Relative to Smoking Cessation Aids

Because FDA’s MRTPA Draft Guidance recommends that perceived risk be evaluated in comparison to therapeutic nicotine replacement products, respondents were asked about the health risks of Camel Snus compared to nicotine replacement products (Question 5a on the survey). There was no mention of cessation products or other nicotine products in the proposed advertisement. Across all respondents, 62% (60.3%-63.7%) endorsed the statement that “Camel Snus is NOT a safer alternative than products that are used to quit tobacco such as gum, patches, and lozenges” (respondents were asked to identify the true statement). Most of the remaining respondents were unsure of the correct response (25%; 23.4%-26.6%), as this issue was not directly addressed in the proposed advertisement, and others considered the statement untrue (14%; 12.7%-15.3%). A possible explanation for incorrect responses (*i.e.*, cessation products are not safer than Camel Snus) could be that respondents, like many in the population, had pre-existing misperceptions about the safety of nicotine replacement therapies (NRTs). Studies have demonstrated widespread misperceptions about the safety and addictive potential of NRT overall and relative to cigarettes ([Ferguson et al. 2011](#); [Shiffman et al. 2008](#); [Silla et al. 2014](#)).

Subgroups of interest

Among potential quitters, for whom NRT would be an appropriate consideration, 56% (49.1%-62.9%) endorsed the statement (*i.e.*, Camel Snus is not a safer alternative to products used to quit tobacco), while 24% (17.8%-30.2%) did not, and 20% (14.3%-25.7%) were unsure whether Camel Snus is a safer alternative than nicotine replacement products. Those with limited health literacy were the subgroup most likely to indicate that they did not know the answer (32%; 29.1%-34.9%) and were the least likely to endorse the statement (48%; 44.9%-51.1%). Across the different subgroups, former tobacco users were most likely to endorse the statement (65%; 62.3%-67.7%) (for detailed results across the different subgroups, see [Table 9](#) and [Appendix B, Table 8](#) in *Camel SNUS Modified Risk Messaging: Comprehension and Perceptions among Tobacco Users and Non-Users – Third Execution of Consumer Testing – Amended Final Report*).

6.2.6.2.8 Respondents' Beliefs about the Health Risks of Camel Snus Relative to Quitting All Tobacco Use

In accordance with the Draft Guidance for MRTPAs, respondents were also asked about the safety of Camel Snus relative to stopping use of all tobacco products (Question 5b on the survey). Although the proposed advertisement did not explicitly state that cessation of all tobacco use is safer than Camel Snus, it did state *“If you’re a smoker concerned about the health risks from smoking, the best choice is to quit”* and *“No tobacco product is safe.”* (Italics added.) In addition, one-quarter of the full sample viewed the proposed advertisement with the government-mandated warning label statement *“WARNING: This product is not a safe alternative to cigarettes.”*

Across all respondents, 69% (67.3%-70.7%) correctly responded that “Camel Snus is NOT a safer alternative than quitting tobacco entirely”; 15% (13.7%-16.3%) answered incorrectly, and 17% (15.6%-18.4%) were unsure of the correct response.

Subgroups of interest

Among current tobacco users and potential quitters – two subgroups for whom this particular message is most relevant – 64% (60.8%-67.2%) and 62% (55.1%-68.9%) answered correctly, approximately one-quarter in each of these groups (21% [18.2%-23.8%] and 25% [18.6%-31.4%]) answered incorrectly, and 15% (12.6%-17.4%) and 12% (7.4%-16.6%) were unsure of whether Camel Snus is a safer alternative to quitting all tobacco use.

Comprehension of this message (*i.e.*, quitting all tobacco use is safer than Camel Snus) is also important for former tobacco users who might be tempted to resume tobacco use with Camel Snus. In this group, 74% (71.5%-76.5%) answered correctly, 12% (10.2%-13.8%) answered incorrectly, and 14% (12.0%-16.0%) were unsure of the correct response. Those with limited health literacy had the lowest proportion of correct responses (53%; 49.9%-56.1%) and the highest proportion of “don’t know/unsure” responses (28%; 25.2%-30.8%) (Table 9 and Appendix B, Table 9 in Camel SNUS Modified Risk Messaging: Comprehension and Perceptions among Tobacco Users and Non-Users – Third Execution of Consumer Testing – Amended Final Report).

6.2.6.2.9 Respondents' Beliefs about the Addictiveness of Camel Snus

6.2.6.2.9.1 Respondents' Understanding of the Proposed Advertising – Camel Snus is Addictive

Respondents' perceptions about the addictiveness of Camel Snus were assessed in two ways: a dichotomous qualitative question, and a quantitative rating question.

Qualitative assessment

Respondents' understanding that Camel Snus is addictive was assessed in a question that simply asked “Is Camel Snus, which contains nicotine, addictive?” (yes/no/don’t know response options; Question 1a on the survey). Among all respondents, 82% (80.5%-83.5%) correctly stated that

Camel Snus is addictive. Most of the remainder (12%; 10.8%-13.2%) were unsure of the correct response, while 7% (6.0%-8.0%) indicated it is not addictive.

Subgroups of interest

Across the subgroups, those with limited health literacy had the lowest proportion of correct responses for this particular question (67%; 64.0%-70.0%) and the highest proportion of don't know responses (20%; 17.5%-22.5%) as well as incorrect responses (13%; 10.8%-15.2%). Given the prominent and explicit statements in the proposed advertisement regarding the addictive potential of Camel Snus that were virtually identical to the question itself, as well as the government-mandated addiction warning label statement displayed to one-quarter of participants, it is unclear why some respondents answered incorrectly or were unsure of the correct response.

Among young adults ages 18-24, 84% (78.5%-89.5%) answered correctly and approximately equal proportions were unsure of the correct response (9%; 4.7%-13.3%) or answered incorrectly (7%; 3.1%-10.9%). Understanding that Camel Snus is addictive is also important for experimenters, who may ultimately progress to regular tobacco use – 75% (69.2%-80.8%) answered correctly, 15% (11.1%-18.9%) were unsure of the correct response, and 12% (6.9%-17.1%) answered incorrectly (for detailed results across the different subgroups, see [Table 8](#) and [Appendix A](#) in Camel SNUS Modified Risk Messaging: Comprehension and Perceptions among Tobacco Users and Non-Users – Third Execution of Consumer Testing – Amended Final Report).

Quantitative assessment

An additional assessment of the perceived addictiveness of Camel Snus was obtained by asking respondents to quantitatively rate the addictive potential of Camel Snus on a 1-7 scale ranging from “not at all addictive” to “extremely addictive” (Question 2f on the survey).

As shown in [Table 6.2.6-4](#), respondents rated the addictiveness of Camel Snus at 6.1 on the 7-point scale, indicating a substantial degree of perceived addictiveness. Indeed, this risk rating was higher than the ratings assigned by respondents for perceived risk of the two diseases for which reduced risk was claimed ([Table 6.2.6-1](#) above).

Table 6.2.6-5: Respondents’ (n=4,906) Beliefs about the Addictiveness of Camel Snus, Cigarette Smoking, and Smokeless Tobacco

	Camel Snus	Cigarette Smoking	Smokeless Tobacco (other than Camel Snus)
How addictive *	6.1** (6.05-6.15)	6.6 (6.56-6.64)	6.3 (6.26-6.34)

* Rated on a 7-point scale ranging from 1 (“not at all addictive”) to 7 (“extremely addictive”)

** Mean risk rating (95% confidence interval in parentheses)

Subgroups of interest

The ratings of addictiveness of Camel Snus across subgroups were consistent with those for the full sample – each subgroup, respectively, rated the addictive potential of Camel Snus as high – 6.1 (5.91-6.29) for young adults ages 18-24; 6.1 (6.02-6.18) for never tobacco users; 5.6 (5.38-5.82) for experimenters; and 5.7 (5.6-5.8) for those with limited health literacy (for detailed results across the different subgroups, see [Table 9](#) and [Appendix B, Table 4](#) in Camel SNUS Modified Risk Messaging: Comprehension and Perceptions among Tobacco Users and Non-Users – Third Execution of Consumer Testing – Amended Final Report).

6.2.6.2.9.2 Respondents’ Beliefs about the Addictiveness of Camel Snus Relative to Cigarette Smoking and Other Smokeless Tobacco Products

Respondents were also asked to give quantitative ratings of the addictive potential of cigarette smoking and other smokeless tobacco use, which allowed for assessment of respondents’ perceptions of relative addictiveness. The ratings were made on a 1-7 scale ranging from “not at all addictive” to “extremely addictive” (Question 2f on the survey). The proposed advertisement seen by respondents explicitly stated that Camel Snus is addictive, but did not provide comparative information on addiction relative to cigarette smoking or other smokeless tobacco.

As shown in [Table 6.2.6-5](#) above, respondents rated the addictiveness of Camel Snus lower than that of other smokeless tobacco products and cigarette smoking, respectively. The perception of lower addictive potential was modest, amounting to 0.5 points on the 7-point scale when compared to smoking, and 0.2 points on that scale when compared to other smokeless tobacco products.

Subgroups of interest

As in the full sample, the perceived addictiveness of Camel Snus was always rated lower than that of cigarette smoking and other smokeless tobacco across each of the different subgroups. The ratings suggest that respondents believed that Camel Snus is clearly addictive, though slightly less addictive than either cigarette smoking or other smokeless tobacco use ([Appendix B, Tables 4, 5, and 6](#) in Camel SNUS Modified Risk Messaging: Comprehension and Perceptions among Tobacco Users and Non-Users – Third Execution of Consumer Testing – Amended Final Report).

6.2.6.2.10 Additional Messages in the Interest of Public Health

6.2.6.2.10.1 Respondents’ Understanding of the Proposed Advertising – Switching Completely to Camel Snus to Reduce Health Risks

The reduction of risk associated with switching from cigarette smoking to Camel Snus is best achieved by switching completely from smoking to Camel Snus. To communicate this concept, the proposed modified risk advertisement stated “*Smokers who switch completely from cigarettes to Camel Snus can greatly reduce their risk of lung cancer and respiratory disease.*” In addition, other statements in the proposed advertisement stress “switching” to Camel Snus:

“Switch completely from cigarettes to Camel Snus”; “I’m a smoker. Why should I switch?”; “But if you’re not going to quit using tobacco products, you should think about switching to Camel Snus.” (Emphasis added throughout.) Therefore, a question was included to assess whether respondents understood that smokers’ health risks are reduced only if they quit smoking completely and use Camel Snus *instead of* cigarettes. Respondents were asked what action was needed in order for smokers to receive a health benefit from using Camel Snus, and two response options were provided: 1) stop smoking completely and use Camel Snus instead; and 2) continue to smoke, but use Camel Snus as well (Question 1a2 on the survey).

More than three-quarters (78%; 76.5%-79.5%) of all respondents indicated that smokers should “stop smoking completely and use Camel Snus instead” in order to receive a health benefit, while very few respondents indicated that Camel Snus should be used while continuing to smoke (4%; 3.9%-4.7%). A total of 18% (16.6%-19.4%) were unsure of the correct response to this question.

Subgroups of interest

Comprehension of the message about complete switching is particularly important for current tobacco users and potential quitters, who must understand that completely stopping smoking is required to receive a health benefit when using Camel Snus. Among current tobacco users, 77% (74.1%-79.9%) indicated that smokers should switch completely to Camel Snus; very few indicated that Camel Snus should be used while continuing to smoke (8%; 6.0%-10.0%); and 16% (13.5%-18.5%) were unsure. Among potential quitters, 78% (72.1%-83.9%) indicated that smokers should switch completely to snus; 11% (6.5%-15.5%) indicated that Camel Snus should be used while continuing to smoke; and 12% (7.5%-16.5%) were unsure of the correct response.

Across the other subgroups, only small percentages indicated that Camel Snus should be used while continuing to smoke (from a low of 2% for former tobacco users to a high of 11% for experimenters and potential quitters). Those with limited health literacy were least likely to say that complete switching to Camel Snus was necessary (65%; 62.1%-67.9%) and most likely to say they did not know the answer (28%; 25.2%-30.8%); in this subgroup, very few indicated that Camel Snus should be used while continuing to smoke (6%; 4.5%-7.5%) (for detailed results across the different subgroups, see [Appendix A, Table 2](#) in Camel SNUS Modified Risk Messaging: Comprehension and Perceptions among Tobacco Users and Non-Users – Third Execution of Consumer Testing – Amended Final Report).

6.2.6.2.10.2 Respondents’ Understanding of the Proposed Advertising Emphasizing that Quitting Smoking is the Best Choice

For smokers concerned about the health risks of smoking, it is important that they understand that Camel Snus reduces some health risks compared to cigarette smoking, but quitting smoking is the best way to eliminate those risks. Understanding of this message aims to mitigate the possibility that smokers who might otherwise quit might adopt Camel Snus instead of quitting tobacco completely. Accordingly, the proposed advertisement included the following statement: *“If you’re a smoker concerned about the health risks from smoking, the best choice is to quit.”* (Italics added.) To assess understanding of this concept, respondents were asked whether

“Quitting is the best choice for a smoker who is concerned about health risks from smoking” (yes/no/don’t know response options; Question 1a on the survey).

A strong majority of all respondents (89%; 87.8%-90.2%) correctly understood this message, with small proportions indicating the wrong answer (6%; 5.1%-6.9%) or being unsure of the correct answer (5%; 4.1%-5.9%).

Subgroups of interest

There was also excellent comprehension of the “best choice is to quit” message among the subgroups for whom this message is most relevant – 89% (86.8%-91.2%) of current tobacco users, 94% (92.6%-95.4%) of former tobacco users, and 92% (88.3%-95.7%) of potential quitters indicated that quitting is the best choice for a smoker concerned about the health risks from smoking. Across the subgroups, those with limited health literacy had the lowest proportion of correct responses for this particular question (78%; 75.3%-80.7%) and the highest proportion of “don’t know” responses (10%; 8.1%-11.9%), but still showed good comprehension (for the full results across all subgroups, see [Table 8](#) and [Appendix A, Table 1](#) in Camel SNUS Modified Risk Messaging: Comprehension and Perceptions among Tobacco Users and Non-Users – Third Execution of Consumer Testing – Amended Final Report).

6.2.6.2.10.3 Respondents’ Understanding of the Message that Former and Never Users of Tobacco Products Should Not Use Camel Snus

The proposed advertisement indicated that Camel Snus should not be used by non-tobacco users (both never and former users): “*Adults who do not use or who have quit using tobacco products should not start.*” To ensure respondents understood that Camel Snus should not be used by non-tobacco users, they were asked “Should adults who do not use or who have quit using tobacco products start using Camel Snus?” (yes/no/don’t know response options; Question 1a on the survey).

This message was correctly understood by 84% (82.8%-85.2%) of respondents overall; a small percentage (6%; 5.1%-6.9%) provided the incorrect response (yes); and 10% (8.9%-11.1%) were unsure of the correct response even though this question mirrored the statement in the advertisement.

Subgroups of interest

This message is particularly important for former tobacco users and never tobacco users, who should not start using any tobacco product, including Camel Snus. The message that Camel Snus should not be used by those who don’t use tobacco products was well understood by former tobacco users (89%; 87.2%-90.8%) and never tobacco users (83%; 80.8%-85.2%). In the former and never tobacco user subgroups, those unsure of the correct response were 7% (5.6%-8.4%) and 11% (9.2%-12.8%), respectively. Among those with limited health literacy, 72% (69.2%-74.8%) answered correctly, but 17% (14.7%-19.3%) were unsure of the correct response (for the full results across the subgroups, see [Table 8](#) and [Appendix A, Table 1](#) in Camel SNUS Modified Risk

Messaging: Comprehension and Perceptions among Tobacco Users and Non-Users – Third Execution of Consumer Testing – Amended Final Report).

6.2.6.3 Conclusions

The “Camel Snus Modified Risk Messaging: Comprehension and Perceptions among Tobacco Users and Non-Users – Third Execution of Consumer Testing” study was conducted in accordance with the FDA’s MRTPA Draft Guidance to evaluate the effects of the proposed modified risk advertising for Camel Snus on current tobacco users’ and non-users’ understanding and perceptions. Overall, the results of this study suggest good comprehension of the proposed modified risk advertising for Camel Snus, and little indication that respondents were misled by the messaging. Across the different questions posed to respondents, although less than perfect comprehension was demonstrated, strong majorities showed understanding of the absolute and relative risks of Camel Snus in the context of the following messaging:

- Camel Snus poses less risk than cigarette smoking for particular diseases (*i.e.*, lung cancer and respiratory disease).
- However, Camel Snus is not completely without risk.
- Camel Snus is not a safer alternative than NRTs that are used to quit tobacco.
- Camel Snus is not a safer alternative than quitting tobacco entirely.
- Camel Snus is addictive.
- Current smokers who switch completely from cigarettes to Camel Snus can greatly reduce their health risks.
- Quitting all tobacco products is the best choice for current tobacco users concerned about health risks.
- Former and never users of tobacco products should not use Camel Snus.

A key message conveyed in the proposed advertisement was that Camel Snus reduces the health risks of lung cancer and respiratory disease. This message was understood by a majority of respondents – about two-thirds indicated that Camel Snus carried less risk (but still some risk) for these conditions, and average ratings of risk were lower for Camel Snus relative to cigarette smoking. Thus, the proposed advertisement generally conveyed the concept of reduced risk for Camel Snus.

Importantly, respondents understood that Camel Snus was not completely safe and still carried some risk. Only 10% considered Camel Snus to be without risk for the diseases assessed, and perceived risk ratings consistently averaged above 4 on a 7-point risk scale (where 1 meant no risk), implying considerable risk. Thus, respondents viewing the proposed advertisement did not over-extend the messaging to conclude that Camel Snus was completely safe. This is an

important finding, as it supports the idea that smokers may benefit from switching from cigarette smoking to Camel Snus, but that non-tobacco users should not adopt use of Camel Snus, as this may subject them to risk.

Similarly, respondents did not over-generalize the stated risk reduction to general health, rating the risk of Camel Snus to "generally poor health" at 5.8 on the 7-point risk scale, where 1 represented no risk. In other words, respondents considered that use of Camel Snus was a considerable risk to health, beyond the specific diseases mentioned. The advertisement did not address the effect of Camel Snus on any diseases other than lung cancer and respiratory disease, leading 85% to conclude that it either did not reduce the risk of other diseases (37%) or that they did not know its effect on other diseases (48%). At the same time, when asked to quantitatively rate the risk of Camel Snus for heart disease, respondents rated it as lower than the risk of cigarette smoking. Yet respondents rated the risk of Camel Snus for oral cancer almost as high as that of smoking. This suggests that respondents were not generalizing the explicit modified risk claims to all smoking-related diseases, but were exercising their intuitions about disease causation in making their risk ratings. Research suggests, for example, that consumers believe that since smokeless tobacco comes in contact with the mouth, but, unlike smoking, is not inhaled, that its effects would be greater on oral cancer than on diseases of the respiratory system (lung cancer and respiratory disease) (Choi *et al.* 2012; Pepper *et al.* 2015). Respondents also generally understood that Camel Snus is addictive. Thus, the modified risk messaging in the proposed advertisement led to respondent beliefs that were typically neither overstated nor over-generalized.

Indeed, respondents' assumptions about the expected reduction in risk of switching from cigarette smoking to Camel Snus appeared to be quite modest, likely understating the actual risk reduction, particularly for lung cancer and respiratory diseases. Further, given the explicit statements in the advertisement that Camel Snus reduced the risk of lung cancer and respiratory disease, it was striking that substantial minorities of respondents stated that Camel Snus carried the *same* risk as continuing to smoke: 19% believed this for both lung cancer and respiratory disease. Respondents formulated their responses not just based on what they read and understood from the advertisement itself, but additionally were influenced by pre-existing beliefs and intuitions. Multiple findings indicate that many Americans believe that smokeless tobacco is as dangerous or more dangerous than smoking (Fong *et al.* 2016; Kaufman *et al.* 2014; Kiviniemi and Kozlowski 2015; Liu *et al.* 2015; O'Connor *et al.* 2005a; Regan *et al.* 2012; Smith *et al.* 2007; Wray *et al.* 2012).

Thus, the opinions provided by respondents after exposure to the advertisement must be seen in the context of the prevailing public misperception that smokeless tobacco, including snus, is at least as harmful as smoking (Fong *et al.* 2016; Kaufman *et al.* 2014; Kiviniemi and Kozlowski 2015; Liu *et al.* 2015; Regan *et al.* 2012; Wray *et al.* 2012), especially for oral cancer (Choi *et al.* 2012; Pepper *et al.* 2015). Given this prevailing view, and the skepticism with which reduced risk information is received (Borland *et al.* 2012), it is understandable that some respondents continued to believe that Camel Snus was as harmful as smoking. In practice, modified risk messaging may need repetition and endorsement from multiple credible sources to become

more persuasive and believable to consumers, so as to change their beliefs and to support changes in tobacco use behavior.

Respondents not only did not overstate the risk reduction attributable to Camel Snus, but they also did not over-generalize it to all other smokeless products. The risk of other smokeless tobacco products was rated higher than that of Camel Snus for each of the four diseases mentioned in the advertisement. Nor did most respondents believe that Camel Snus was as safe as nicotine replacement medications, though this comparison was less well understood than the comparison to cigarette smoking. This is not surprising in light of shared misperceptions about the harms of nicotine even in FDA-approved medications (Borland *et al.* 2011; Ferguson *et al.* 2011; Smith *et al.* 2007), and the widespread belief that nicotine is a primary harmful ingredient in tobacco and NRT products (Bansal *et al.* 2004; Ferguson *et al.* 2011; Mooney *et al.* 2006). Mitigating public misperceptions about Camel Snus may benefit from addressing broader misconceptions about nicotine and its role in smoking-related harms (Borland *et al.* 2011; Borland *et al.* 2012; Ferguson *et al.* 2011; Regan *et al.* 2012).

6.2.6.3.1 Subgroups

Certain messages in the proposed advertisement are of special relevance to particular subgroups. Accordingly, comprehension and perceptions were also evaluated in subgroups of interest. The results showed good comprehension for most of these message-by-subgroup pairings. For example, a strong majority of current tobacco users (89%) understood the message that quitting smoking is the best option for smokers concerned about health risks. This suggests that messages about reduced risk would not deter smokers from quitting, and that using Camel Snus would not be seen as an adequate substitute for quitting. Over three-quarters of current tobacco users (77%) understood that smokers' health risks are reduced only if they stop smoking completely and use Camel Snus instead of cigarettes. Few (8%) said that Camel Snus would confer a health benefit if used while smoking. Thus, respondents generally understood that the benefit of Camel Snus would come from substituting Camel Snus for smoking, and that the optimal course was to stop smoking without the use of Camel Snus.

Further, current tobacco users who were potential quitters had excellent understanding (92%) of the message that quitting is the best choice for smokers, suggesting that the offer of Camel Snus would not lead them to think of Camel Snus as an alternative to quitting, and thus deter them from quitting. Similarly, subgroups that were not current tobacco users – former tobacco users and never users – well understood that non-users should not use Camel Snus (89% and 83%, respectively), suggesting that the messaging would not attract initiation among these non-user groups.

The study also evaluated comprehension and perceptions among individuals with limited health literacy.

Studies have consistently demonstrated that limited health literacy is associated with lower comprehension and understanding of consumer communications including prescription and over-the-counter drug labels (Davis *et al.* 2006; Raymond *et al.* 2002; Shiffman *et al.* 2011; Wolf *et al.*

2006) and FDA risk communications (McCormack *et al.* 2016). Consistent with this, respondents with limited health literacy typically showed less understanding of the messages conveyed by the proposed advertisement, and were consistently more likely than any other subgroup to answer "don't know/not sure" when such options were available. The advertisement text included simple, direct wording, and used devices such as bullet points and white space, that are recommended for effective communication across the spectrum of health literacy (CDC 2009; Plain Language Action and Information Network 2011). The proposed advertisement aims to communicate multiple messages, which can complicate communication, particularly on a single, brief exposure. It may be that repeated and prolonged exposure, or expression of the messages in different ways from different sources, may help communicate the messages to individuals with limited health literacy. In any case, even those with limited health literacy showed reasonable comprehension of key messages, notably *not* being led to think that use of Camel Snus carries no risk, that non-smokers should use Camel Snus, that Camel Snus is not addictive, or that smokers should simply add use of Camel Snus to their smoking. The results suggest that even individuals with limited health literacy would not be put at risk by the proposed advertisement with the modified risk messaging.

Comprehension among ethnic minority respondents was somewhat lower overall than for Caucasian respondents. This may be because of the association between health literacy and minority status. Studies have shown that racial and ethnic minorities, particularly African Americans and Hispanics, have a higher prevalence of limited health literacy (IOM 2004; Kutner *et al.* 2006; Rudd 2007).

6.2.6.3.2 Limitations and Strengths

Like any study, this study had limitations. The sample was drawn from an opt-in online panel, and thus may not be fully representative of the U.S. population, not all of whom have internet access or join online panels. However, strong majorities of Americans are now online (Perrin and Duggan 2015), and online panels can produce reasonable estimates (Farrell and Petersen 2010). Moreover, the sample was diverse, and was recruited and weighted to represent the demographics of the U.S. population.

The proposed Camel Snus advertisement is intended to be displayed in multiple media, but in this study the advertisement was evaluated via an online, on-screen display in a research context. However, such methods are often used to evaluate communications (Sullivan *et al.* 2015), and there is little reason to think the results are not generalizable to other media. The study measured the effects of a single exposure of the proposed modified risk advertising for Camel Snus during the course of a study, as opposed to the effects of multiple exposures over time in the real world in the context of advertising. It is possible that repeated exposure over time to the modified risk advertising would lead to improved comprehension and understanding of the absolute and relative health risks of Camel Snus and cigarette smoking (Borland *et al.* 2012). Nonetheless, the results from this study indicate good comprehension of the proposed modified risk advertising for Camel Snus. The advertisement communicated a great deal of presumably new information about Camel Snus and its risk reduction potential relative to cigarette smoking.

Importantly, some of the information in the proposed advertisement was likely at odds with respondents' pre-existing beliefs, as research consistently shows that people believe that smokeless tobacco products are at least as hazardous as cigarettes (Fong *et al.* 2016; Kaufman *et al.* 2014; Kiviniemi and Kozlowski 2015; Liu *et al.* 2015; Regan *et al.* 2012; Wray *et al.* 2012). That respondents applied their own beliefs, and not just their understanding of the advertisement, was evident in the pattern of responses (*see above*). Thus, some information may have been understood, but not believed (Borland *et al.* 2012). The fact that the source of the information was a tobacco company may have made the information less credible, as tobacco companies now rank among the least credible information sources (Byrne *et al.* 2012; Harris Interactive 2013). Multiple exposures to relevant messages, and support of messages from multiple credible sources, may help overcome people's current beliefs and misperceptions about smokeless tobacco. Finally, the study itself was long and may have led to respondent fatigue.

The study also had considerable strengths. The sample was large, diverse, and sampled and weighted to match the demographics of U.S. adults. It included a broad range of demographics, including a substantial representation of individuals with limited health literacy. The assessment covered a broad range of messages identified by FDA in its Draft Guidance on MRTP applications, and thus addresses the issues of concern for modified risk messaging. The study sampled current, former, and never users of tobacco products, and also analyzed responses from important subgroups based on demographics or tobacco use history. Survey questions and algorithms used to characterize subgroups were drawn from well-established norms in the published literature. Questions about relative risk of Camel Snus were asked in two different ways, and generated consistent, convergent results.

6.2.6.4 Summary – Execution 3

This study assessed adults' responses to proposed Camel Snus modified risk advertising that carried a risk reduction message, and also conveyed important messages aimed to mitigate potential unintended consequences of modified risk messaging. The results showed that individuals exposed to such messages understood that Camel Snus carries less risk than cigarette smoking, but still carries considerable risk and is not completely safe. They understood that Camel Snus is addictive, that quitting smoking is the best choice, and that persons who do not already use tobacco should not use Camel Snus. In short, the proposed advertising was successful in communicating reduced risk while avoiding over-generalization of the risk messaging and mitigating any potential for the messaging to deter quitting or promote initiation. In sum, the proposed advertising was understood.