

6.5 Tabulated Index of Studies and Analyses

Consistent with the FDA's MRTP Draft Guidance, RJRT has prepared a tabulated index of studies and analyses submitted in support of this MRTP Application. The tabulated index is organized according to the following five key areas of investigation:

- Health Risks of the Tobacco Product;
- Effect on Tobacco Use Behavior among Current Users;
- Effect on Tobacco Use Initiation among Non-Users;
- Effect of Marketing on Consumer Understanding and Perceptions; and
- Effect on the Population as a Whole.

The index is further organized by study type (*i.e.*, product analyses, nonclinical studies, studies in adult human subjects, and secondary data analyses and modeling) and identifies each study and analysis by name and section. The index also includes hypertext links to the studies, analyses, scientific literature, and other references and supporting documents submitted in support of this Application.

6.5.1 Index organized by key areas of investigation

Table 6.5.1-1: Health risks of the tobacco product

Document/File Name	Study Title	MRTPA Section
CN49730C Final Report	28-Day Repeated Dose Toxicity Study of Tobacco Blend and Aqueous Tobacco Extract in Wistar Han Rats (April 2009)	2.9, 6.1.4
CN49730D Final Report	28-Day Repeated Dose Toxicity Study of Tobacco Blend and Aqueous Tobacco Extract in CD-1 Mice (April 2009)	2.9, 6.1.4
CN49730E Amended Final Report	90-Day Repeated Dose Subchronic Toxicity Study of Tobacco Blend and Aqueous Tobacco Extract in Wistar Han Rats (April 2012)	2.9, 6.1.4
CN49730F Amended Final Report	90-Day Repeated Dose Toxicity Study of Tobacco Blend and Aqueous Tobacco Extract in CD-1 Mice (April 2012)	2.9, 6.1.4
CN49730G Final Carcinogenicity Report	2-Year Chronic Toxicology/Carcinogenicity Feeding Study of Tobacco Blend and Aqueous Tobacco Extract in Wistar Han Rats: 2-Year Chronic Carcinogenicity Study (April 2012)	2.9, 6.1.4
CN49730G Final Toxicity Report	2 Year Chronic Toxicology/Carcinogenicity Feeding Study of Tobacco Blend and Aqueous Tobacco Extract in Wistar Han Rats: 12 Month Repeated Dose Chronic Toxicity Study (January 2011)	2.9, 6.1.4
CSD0804	Assessment of Mouth-Level Exposure to Tobacco Constituents in U.S. Snus Consumers (March 2013)	2.9, 3.4-3.5, 6.1.2
CSD0901	Switching from usual brand cigarettes to CAMEL "SNUS," CAMEL Dissolvable Tobacco "STICKS," "STRIPS," OR "ORBS," Dual Use Of Usual Brand Cigarettes And Snus, Or Tobacco Abstinence – A Multi-Center Evaluation Of Select Modern Smoke-Free Tobacco Products (July 2, 2014)	2.9, 3.4-3.5, 6.1.2
CSD0904	Post-Market Surveillance of Tobacco Products: A Multicenter Clinical Trial of Natural Adopters of Cigarettes, Moist Snuff, Camel SNUS, and Dual Use (December 16, 2013)	2.9, 3.4-3.5, 6.1.2, 6.1.3
CSD0905	Ambulatory Study Comparing Ad Libitum Use of Usual Brand Cigarettes to Dual Use of Camel Snus with Reduced Smoking (December 14, 2010)	2.9, 3.4-3.5, 6.1.2

Document/File Name	Study Title	MRTPA Section
CSD0914	Assessment of Serum Nicotine from Modern Smoke-Free Tobacco Products (October 25, 2011)	2.9, 6.1.2
CSD1010	A Randomized, Multicenter Clinical Trial to Compare Smoking Cessation Rates with Camel Snus, with and without Smokeless Tobacco Health-Related Background Information, and a Nicotine Lozenge (August 20, 2014)	2.5, 2.9, 3.4-3.5, 6.1.2
CSD1101	Assessment of Smokers' Nicotine Uptake and Urge to Smoke after Use of Smokeless Tobacco Products (January 7, 2013)	2.9, 6.1.2
HSD0702	Switching from Usual Brand Cigarettes to a Tobacco Heating Cigarette or Snus—A Multi-Center Evaluation of Health-Related Quality of Life Assessments and Biomarkers of Exposure and Harm (November 23, 2009)	2.9, 3.4-3.5, 6.1.2
M100 MN	Toxicology of Smokeless Tobacco Products: In Vitro Micronucleus Assay. Labstat International ULC Test Report (January 12, 2009)	2.9, 6.1.3
M100 NRU	Toxicology of Tobacco Products: Neutral Red Uptake Cytotoxicity. Labstat International ULC Test Report (January 9, 2009)	2.9, 6.1.3
M125	Toxicology of Tobacco Products: Sister Chromatid Exchange Genotoxicity. Labstat International ULC Test Report (April 21, 2010)	2.9, 6.1.3
M194A-GLP	Determination of Mutagenic Response of Camel Snus and Other Tobacco Products. Final Study Report. Labstat (July 17, 2014)	2.9, 6.1.3
M194B-GLP	Determination of Cytotoxic Response of Camel Snus and Other Tobacco Products. Final Study Report. Labstat (July 15, 2014)	2.9, 6.1.3
M97	Toxicology of Smokeless Tobacco Products: Bacterial Reverse Mutagenicity. Labstat International ULC Test Report (October 9, 2008)	2.9, 6.1.3
M97 Supplemental Report	Toxicology of Smokeless Tobacco Products: Bacterial Reverse Mutagenicity. Labstat International ULC Supplemental Analysis Report (January 2, 2012)	6.1.3
RDM KWF 2011, 003	Summary of Labstat Project M125/RJRT Project MBIV-014: Sister chromatid exchange assays of smokeless tobacco samples (February 4, 2011)	6.1.3
RDM KWF 2011, 006	Summary of Labstat Project M97: Bacterial mutagenicity (Ames) assays of smokeless tobacco samples (February 3, 2011)	6.1.3

Document/File Name	Study Title	MRTPA Section
RDM KWF 2011, 007	Summary of Labstat Project M100: In vitro micronucleus assays of smokeless tobacco samples (February 7, 2011)	6.1.3
RDM KWF 2011, 008	Summary of Labstat Project M100: Neutral red uptake assays of smokeless tobacco samples (February 3, 2011)	6.1.3
RDM PC 2016 175-a	Conversion of Selected Biomarker Results from Four RJRT Clinical Studies that Investigated Exposures from Camel Snus and Cigarettes in order to Directly Compare the Data with Other Published Results (June 23, 2016)	2.9
RDM PC 2016 274-a	Calculation and Analysis of Acrylamide, Naphthalene, and Phenanthrene Total Equivalents for Biomarker Data and Urine Mutagenicity Unit Conversion in CSD0904 Clinical Study (September 30, 2016)	2.9, 6.1.2
TOX209	Two Week Investigational Study of the Palatability of Smokeless Tobacco Blend and Extract Formulated in NTP-2000 Diets for Rats (May 8, 2009)	2.9, 6.1.4
TOX210	Two Week Investigational Study of the Palatability of Smokeless Tobacco Blend and Extract Formulated in NTP-2000 Diets for Mice (May 1, 2009)	2.9, 6.1.4
TOX213	Two Week Repeat Investigational Study of the Palatability of Smokeless Tobacco Blend and Extract Formulated in NTP-2000 Diets for Mice at Higher Doses (May 8, 2009)	2.9, 6.1.4

Table 6.5.1-2: Effect on tobacco use behavior among current users

Document/File Name	Study Title	MRTPA Section
Amended LoU Final Report - Execution 1	Camel SNUS Modified Risk Messaging: Likelihood of Use among Tobacco Users and Non-Users – First Execution of Consumer Testing – Amended Final Report (October 4, 2016)	2.13, 5, 6.3, 6.4
Amended LoU Final Report - Execution 2	Camel SNUS Modified Risk Messaging: Likelihood of Use among Tobacco Users and Non-Users – Second Execution of Consumer Testing – Amended Final Report (October 4, 2016)	2.13, 5, 6.3, 6.4
Amended LoU Final Report - Execution 3	Camel SNUS Modified Risk Messaging: Likelihood of Use among Tobacco Users and Non-Users – Third Execution of Consumer Testing – Amended Final Report (October 4, 2016)	2.13, 5, 6.3, 6.4
Camel Snus Product Use Report	Camel Snus Product Use Final Report: Demographic Characteristics, Use Behavior Patterns, Use Frequency and Use Rate, RAI Services Company (January 13, 2017)	2.9, 3.4-3.5, 5
Methodology Report for Likelihood of Use Algorithm	New Tobacco Product “Attractiveness” Study: An Algorithm to Predict Usage of New Tobacco Products Prior to Market Launch. Methodological Report. Prepared for RAI Services Center. Prepared by National Analysts Worldwide (April 3, 2012)	2.12, 2.13, 6.3, 6.4
Protocol - LoU Execution 1	Protocol Identifier: RO-BR-2014-03 Camel SNUS Modified Risk Messaging: Likelihood of Use among Tobacco Users and Non-Users (November 21, 2014)	6.3
Protocol - LoU Execution 2	Protocol Identifier: RO-BR-2015-04 Camel SNUS Modified Risk Messaging: Likelihood of Use among Tobacco Users and Non-Users - Second Execution of Consumer Testing (August 5, 2015)	6.3
Protocol - LoU Execution 3	Protocol Identifier: RO-BR-2015-05 Camel SNUS Modified Risk Messaging: Likelihood of Use among Tobacco Users and Non-Users - Third Execution of Consumer Testing (August 5, 2015)	6.3

Table 6.5.1-3: Effect on tobacco use initiation among non-users

Document/File Name	Study Title	MRTPA Section
Amended LoU Final Report - Execution 1	Camel SNUS Modified Risk Messaging: Likelihood of Use among Tobacco Users and Non-Users – First Execution of Consumer Testing – Amended Final Report (October 4, 2016)	2.13, 5, 6.3, 6.4
Amended LoU Final Report - Execution 2	Camel SNUS Modified Risk Messaging: Likelihood of Use among Tobacco Users and Non-Users – Second Execution of Consumer Testing – Amended Final Report (October 4, 2016)	2.13, 5, 6.3, 6.4
Amended LoU Final Report - Execution 3	Camel SNUS Modified Risk Messaging: Likelihood of Use among Tobacco Users and Non-Users – Third Execution of Consumer Testing – Amended Final Report (October 4, 2016)	2.13, 5, 6.3, 6.4
Camel Snus Product Use Report	Camel Snus Product Use Final Report: Demographic Characteristics, Use Behavior Patterns, Use Frequency and Use Rate, RAI Services Company (January 13, 2017)	2.9, 3.4-3.5, 5
Methodology Report for Likelihood of Use Algorithm	New Tobacco Product “Attractiveness” Study: An Algorithm to Predict Usage of New Tobacco Products Prior to Market Launch. Methodological Report. Prepared for RAI Services Center. Prepared by National Analysts Worldwide (April 3, 2012)	2.12, 2.13, 6.3, 6.4
Protocol - LoU Execution 1	Protocol Identifier: RO-BR-2014-03 Camel SNUS Modified Risk Messaging: Likelihood of Use among Tobacco Users and Non-Users (November 21, 2014)	6.3
Protocol - LoU Execution 2	Protocol Identifier: RO-BR-2015-04 Camel SNUS Modified Risk Messaging: Likelihood of Use among Tobacco Users and Non-Users - Second Execution of Consumer Testing (August 5, 2015)	6.3
Protocol - LoU Execution 3	Protocol Identifier: RO-BR-2015-05 Camel SNUS Modified Risk Messaging: Likelihood of Use among Tobacco Users and Non-Users - Third Execution of Consumer Testing (August 5, 2015)	6.3

Table 6.5.1-4: Effect of marketing on consumer understanding and perceptions

Document/File Name	Study Title	MRTPA Section
Amended Final Report - Execution 1	Camel SNUS Modified Risk Messaging: Comprehension and Perceptions among Tobacco Users and Non-Users – First Execution of Consumer Testing – Amended Final Report (August 19, 2016)	2.11, 6.2
Amended Final Report - Execution 2	Camel SNUS Modified Risk Messaging: Comprehension and Perceptions among Tobacco Users and Non-Users – Second Execution of Consumer Testing – Amended Final Report (August 19, 2016)	2.11, 6.2
Amended Final Report - Execution 3	Camel SNUS Modified Risk Messaging: Comprehension and Perceptions among Tobacco Users and Non-Users – Third Execution of Consumer Testing – Amended Final Report (August 19, 2016)	2.11, 6.2
Protocol - Execution 1	Protocol Identifier: RO-BR-2014-02 Camel SNUS Modified Risk Messaging: Comprehension and Perceptions among Tobacco Users and Non-Users (October 17, 2014)	6.2
Protocol - Execution 2	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 (June 24, 2015)	6.2
Protocol - Execution 3	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 (June 24, 2015)	6.2

Table 6.5.1-5: Effect on the population as a whole

Document/File Name	Study Title	MRTPA Section
Statistical Modeling Final Report MRTPA Execution 1	Assessing the Population Health Effects of Camel SNUS and Its Proposed Marketing as a Modified-Risk Tobacco Product – Statistical Modeling Using the Dynamic Population Modeler Execution 1, Final Report (January 27, 2017)	2.13, 6.4
Statistical Modeling Final Report MRTPA Execution 2	Assessing the Population Health Effects of Camel SNUS and Its Proposed Marketing as a Modified-Risk Tobacco Product – Statistical Modeling Using the Dynamic Population Modeler Execution 2, Final Report (January 27, 2017)	2.13, 6.4
Statistical Modeling Final Report MRTPA Execution 3	Assessing the Population Health Effects of Camel SNUS and Its Proposed Marketing as a Modified-Risk Tobacco Product – Statistical Modeling Using the Dynamic Population Modeler Execution 3, Final Report (January 27, 2017)	2.13, 6.4

6.5.2 Index organized by study type

Table 6.5.2-1: Product analyses

Document/File Name	Study Title	MRTPA Section
Chemistry Studies		
M195-GLP	Labstat International ULC. Determination of Smokeless Tobacco HPHC Values for Camel Snus and Other Tobacco Products – M195-GLP. External Co. Report External Co. LSI 2014 113 (April 23, 2014)	2.9, 6.1.5
M273	Labstat International ULC. Characterization of Tobacco-Minor Alkaloids – M273. External Co. Report External Co. LSI 2016 097 (April 6, 2016)	2.9, 6.1.5
RDM JAB 2016,281	Bodnar J. Summary of 2014 and 2015 Smokeless Market Surveys. RJRT Report RDM JAB 2016 281, Barcode R019283 (October 7, 2016)	2.9, 6.1.5
RDM JAB 2016,306	Bodnar J. Summary of 2014 and 2015 Cigarette Market Surveys. RJRT Report RDM JAB 2016 306, Barcode R019275 (November 1, 2016)	2.9, 6.1.5
RDM JMR 2016,235	Rowe JM. Analytical testing of Camel Snus Products. RJRT Report RDM JMR 2016 235, Barcode R019399 (August 22, 2016)	2.9, 6.1.5
Stability Testing		
CSMicrobial	J.A. Hart, N.C. Hall, F.K. St. Charles. Microbial activity of Camel Snus. RJR Report No. RDM JAH 2016, 194, Barcode # R019132 (July 12, 2016)	3.3
CSMoistureBarrier	F.K. St. Charles. Characterization of the moisture barrier properties of Camel Snus packaging. RJR Report No. RDM FKS 2016, 221, Barcode # R019174 (August 8, 2016)	3.3
CSStabilityTest	F.K. St. Charles. Details on a 52 week stability test of Camel Snus. RJR Report No. RDM FKS 2016, 193, Barcode # R019164 (July 11, 2016)	3.3
Wholesale Returned Goods Program	R.J. Reynolds Tobacco Company, American Snuff Company, LLC & R.J. Reynolds Vapor Company. Wholesale Returned Goods Program. Effective Date: (June 27, 2016)	3.3

Table 6.5.2-2: Nonclinical studies

Document/File Name	Study Title	MRTPA Section
<i>In Vitro Studies</i>		
M97	Toxicology of Smokeless Tobacco Products: Bacterial Reverse Mutagenicity. Labstat International ULC Test Report (October 9, 2008)	2.9, 6.1.3
M97 Supplemental Report	Toxicology of Smokeless Tobacco Products: Bacterial Reverse Mutagenicity. Labstat International ULC Supplemental Analysis Report (January 2, 2012)	6.1.3
RDM KWF 2011, 006	Summary of Labstat Project M97: Bacterial mutagenicity (Ames) assays of smokeless tobacco samples (February 3, 2011)	6.1.3
M100 MN	Toxicology of Smokeless Tobacco Products: In Vitro Micronucleus Assay. Labstat International ULC Test Report (January 12, 2009)	2.9, 6.1.3
RDM KWF 2011, 007	Summary of Labstat Project M100: In vitro micronucleus assays of smokeless tobacco samples (February 7, 2011)	6.1.3
M100 NRU	Toxicology of Tobacco Products: Neutral Red Uptake Cytotoxicity. Labstat International ULC Test Report (January 9, 2009)	2.9, 6.1.3
RDM KWF 2011, 008	Summary of Labstat Project M100: Neutral red uptake assays of smokeless tobacco samples (February 3, 2011)	6.1.3
M125	Toxicology of Tobacco Products: Sister Chromatid Exchange Genotoxicity. Labstat International ULC Test Report (April 21, 2010)	2.9, 6.1.3
RDM KWF 2011, 003	Summary of Labstat Project M125/RJRT Project MBIV-014: Sister chromatid exchange assays of smokeless tobacco samples (February 4, 2011)	6.1.3
M194A-GLP	Determination of Mutagenic Response of Camel Snus and Other Tobacco Products. Final Study Report. Labstat (July 17, 2014)	2.9, 6.1.3
M194B-GLP	Determination of Cytotoxic Response of Camel Snus and Other Tobacco Products. Final Study Report. Labstat (July 15, 2014)	2.9, 6.1.3

Document/File Name	Study Title	MRTPA Section
<i>In Vivo Studies</i>		
TOX209	Two Week Investigational Study of the Palatability of Smokeless Tobacco Blend and Extract Formulated in NTP-2000 Diets for Rats (May 8, 2009)	2.9, 6.1.4
TOX210	Two Week Investigational Study of the Palatability of Smokeless Tobacco Blend and Extract Formulated in NTP-2000 Diets for Mice (May 1, 2009)	2.9, 6.1.4
TOX213	Two Week Repeat Investigational Study of the Palatability of Smokeless Tobacco Blend and Extract Formulated in NTP-2000 Diets for Mice at Higher Doses (May 8, 2009)	2.9, 6.1.4
CN49730C Final Report	28-Day Repeated Dose Toxicity Study of Tobacco Blend and Aqueous Tobacco Extract in Wistar Han Rats (April 2009)	2.9, 6.1.4
CN49730D Final Report	28-Day Repeated Dose Toxicity Study of Tobacco Blend and Aqueous Tobacco Extract in CD-1 Mice (April 2009)	2.9, 6.1.4
CN49730E Amended Final Report	90-Day Repeated Dose Subchronic Toxicity Study of Tobacco Blend and Aqueous Tobacco Extract in Wistar Han Rats (April 2012)	2.9, 6.1.4
CN49730F Amended Final Report	90-Day Repeated Dose Toxicity Study of Tobacco Blend and Aqueous Tobacco Extract in CD-1 Mice (April 2012)	2.9, 6.1.4
CN49730G Final Carcinogenicity Report	2-Year Chronic Toxicology/Carcinogenicity Feeding Study of Tobacco Blend and Aqueous Tobacco Extract in Wistar Han Rats: 2-Year Chronic Carcinogenicity Study (April 2012)	2.9, 6.1.4
CN49730G Final Toxicity Report	2 Year Chronic Toxicology/Carcinogenicity Feeding Study of Tobacco Blend and Aqueous Tobacco Extract in Wistar Han Rats: 12 Month Repeated Dose Chronic Toxicity Study (January 2011)	2.9, 6.1.4

Table 6.5.2-3: Studies in adult human subjects

Document/File Name	Study Title	MRTPA Section
Clinical Studies		
CSD0804	Assessment of Mouth-Level Exposure to Tobacco Constituents in U.S. Snus Consumers (March 2013)	2.9, 3.4-3.5, 6.1.2
CSD0901	Switching from usual brand cigarettes to CAMEL “SNUS,” CAMEL Dissolvable Tobacco “STICKS,” “STRIPS,” OR “ORBS,” Dual Use Of Usual Brand Cigarettes And Snus, Or Tobacco Abstinence – A Multi-Center Evaluation Of Select Modern Smoke-Free Tobacco Products (July 2, 2014)	2.9, 3.4-3.5, 6.1.2
CSD0904	Post-Market Surveillance of Tobacco Products: A Multicenter Clinical Trial of Natural Adopters of Cigarettes, Moist Snuff, Camel SNUS, and Dual Use (December 16, 2013)	2.9, 3.4-3.5, 6.1.2, 6.1.3
CSD0905	Ambulatory Study Comparing Ad Libitum Use of Usual Brand Cigarettes to Dual Use of Camel Snus with Reduced Smoking (December 14, 2010)	2.9, 3.4-3.5, 6.1.2
CSD0914	Assessment of Serum Nicotine from Modern Smoke-Free Tobacco Products (October 25, 2011)	2.9, 6.1.2
CSD1010	A Randomized, Multicenter Clinical Trial to Compare Smoking Cessation Rates with Camel Snus, with and without Smokeless Tobacco Health-Related Background Information, and a Nicotine Lozenge (August 20, 2014)	2.9, 3.4-3.5, 6.1.2
CSD1101	Assessment of Smokers’ Nicotine Uptake and Urge to Smoke after Use of Smokeless Tobacco Products (January 7, 2013)	2.9, 6.1.2
RDM PC 2016 175-a	Conversion of Selected Biomarker Results from Four RJRT Clinical Studies that Investigated Exposures from Camel Snus and Cigarettes in order to Directly Compare the Data with Other Published Results (June 23, 2016)	2.9
RDM PC 2016 274-a	Calculation and Analysis of Acrylamide, Naphthalene, and Phenanthrene Total Equivalents for Biomarker Data and Urine Mutagenicity Unit Conversion in CSD0904 Clinical Study (September 30, 2016)	2.9, 6.1.2

Document/File Name	Study Title	MRTPA Section
HSD0702	Switching from Usual Brand Cigarettes to a Tobacco Heating Cigarette or Snus— A Multi-Center Evaluation of Health-Related Quality of Life Assessments and Biomarkers of Exposure and Harm (November 23, 2009)	2.9, 3.4-3.5, 6.1.2
Likelihood of Use Studies		
Amended LoU Final Report - Execution 1	Camel SNUS Modified Risk Messaging: Likelihood of Use among Tobacco Users and Non-Users – First Execution of Consumer Testing – Amended Final Report (October 4, 2016)	2.13, 5, 6.3, 6.4
Amended LoU Final Report - Execution 2	Camel SNUS Modified Risk Messaging: Likelihood of Use among Tobacco Users and Non-Users – Second Execution of Consumer Testing – Amended Final Report (October 4, 2016)	2.13, 5, 6.3, 6.4
Amended LoU Final Report - Execution 3	Camel SNUS Modified Risk Messaging: Likelihood of Use among Tobacco Users and Non-Users – Third Execution of Consumer Testing – Amended Final Report (October 4, 2016)	2.13, 5, 6.3, 6.4
Methodology Report for Likelihood of Use Algorithm	New Tobacco Product “Attractiveness” Study: An Algorithm to Predict Usage of New Tobacco Products Prior to Market Launch. Methodological Report. Prepared for RAI Services Center. Prepared by National Analysts Worldwide (April 3, 2012)	2.12, 2.13, 6.3, 6.4
Protocol - LoU Execution 1	Protocol Identifier: RO-BR-2014-03 Camel SNUS Modified Risk Messaging: Likelihood of Use among Tobacco Users and Non-Users (November 21, 2014)	6.3
Protocol - LoU Execution 2	Protocol Identifier: RO-BR-2015-04 Camel SNUS Modified Risk Messaging: Likelihood of Use among Tobacco Users and Non-Users - Second Execution of Consumer Testing (August 5, 2015)	6.3
Protocol - LoU Execution 3	Protocol Identifier: RO-BR-2015-05 Camel SNUS Modified Risk Messaging: Likelihood of Use among Tobacco Users and Non-Users - Third Execution of Consumer Testing (August 5, 2015)	6.3

Document/File Name	Study Title	MRTPA Section
Consumer Perceptions and Understanding Studies		
Amended Final Report - Execution 1	Camel SNUS Modified Risk Messaging: Comprehension and Perceptions among Tobacco Users and Non-Users – First Execution of Consumer Testing – Amended Final Report (August 19, 2016)	2.11, 6.2
Amended Final Report - Execution 2	Camel SNUS Modified Risk Messaging: Comprehension and Perceptions among Tobacco Users and Non-Users – Second Execution of Consumer Testing – Amended Final Report (August 19, 2016)	2.11, 6.2
Amended Final Report - Execution 3	Camel SNUS Modified Risk Messaging: Comprehension and Perceptions among Tobacco Users and Non-Users – Third Execution of Consumer Testing – Amended Final Report (August 19, 2016)	2.11, 6.2
Protocol - Execution 1	Protocol Identifier: RO-BR-2014-02 Camel SNUS Modified Risk Messaging: Comprehension and Perceptions among Tobacco Users and Non-Users (October 17, 2014)	6.2
Protocol - Execution 2	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 (June 24, 2015)	6.2
Protocol - Execution 3	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 (June 24, 2015)	6.2

Table 6.5.2-4: Secondary data analyses and modeling

Document/File Name	Study Title	MRTPA Section
Statistical Modeling Final Report MRTPA Execution 1	Assessing the Population Health Effects of Camel SNUS and Its Proposed Marketing as a Modified-Risk Tobacco Product – Statistical Modeling Using the Dynamic Population Modeler Execution 1, Final Report (January 27, 2017)	2.13, 6.4
Statistical Modeling Final Report MRTPA Execution 2	Assessing the Population Health Effects of Camel SNUS and Its Proposed Marketing as a Modified-Risk Tobacco Product – Statistical Modeling Using the Dynamic Population Modeler Execution 2, Final Report (January 27, 2017)	2.13, 6.4
Statistical Modeling Final Report MRTPA Execution 3	Assessing the Population Health Effects of Camel SNUS and Its Proposed Marketing as a Modified-Risk Tobacco Product – Statistical Modeling Using the Dynamic Population Modeler Execution 3, Final Report (January 27, 2017)	2.13, 6.4

6.5.3 Index of scientific literature

Document/File Name	Full Reference	MRTPA Section
Abd El Mohsen et al. 1997	Abd El Mohsen MM, Fahim AT, Motawi TMK, and Ismail NA. 1997. Nicotine and stress: effect on sex hormones and lipid profile in female rats. <i>Pharmacol Res</i> 35(3):181-187.	6.1.4
Accortt et al. 2002	Accortt NA, Waterbor JW, Beall C, and Howard G. 2002. Chronic disease mortality in a cohort of smokeless tobacco users. <i>Am. J. Epidemiol.</i> 156: 730-737.	6.0-6.1.1
Accortt et al. 2005	Accortt NA, Waterbor JW, Beall C, and Howard G. 2005. Cancer incidence among a cohort of smokeless tobacco users (United States). <i>Cancer Causes Control</i> 16:1107-1115.	2.9, 6.0-6.1.1
Agaku et al. 2013	Agaku IT, Ayo-Yusuf OA, Vardavas CI, Alpert HR, and Connolly GN. 2013. Use of conventional and novel smokeless tobacco products among US adolescents. <i>Pediatrics</i> 132(3):e578-586.	2.12
Albertini et al. 1988	Albertini RJ, Sullivan LM, Berman JK, Greene CJ, Stewart JA, Silveira JM, and O'Neill JP. 1988. Mutagenicity monitoring in humans by auto radiographic assay for mutant T-lymphocytes. <i>Mutation Research</i> 204:481-492.	6.1.3
Ames et al. 1975	Ames BN, McCann J, and Yamasaki E. 1975. Methods for detecting carcinogens and mutagens with the Salmonella/mammalian-microsome mutagenicity test. <i>Mutation Research</i> 31:347-363.	6.1.3
Andersson et al. 1994	Andersson G, Björnberg G, and Curvall M. 1994. Oral mucosal changes and nicotine disposition in users of Swedish smokeless tobacco products: a comparative study. <i>J Oral Pathol Med</i> 23:161-167.	2.8, 6.1.2
Andreoli et al. 2003	Andreoli C, Gigante D, and Nunziata A. 2003. A review of <i>in vitro</i> methods to assess the biological activity of tobacco smoke with the aim of reducing the toxicity of smoke. <i>Toxicology in Vitro</i> 17:587-594.	6.1.3
Antoniades et al. 1984	Antoniades D, Niukian K, Schwartz, J and Shklar F. 1984. Effects of smokeless tobacco on the immune system of Syrian hamsters. <i>J Oral Med</i> 39(3):136-141.	6.1.4

Document/File Name	Full Reference	MRTPA Section
Apelberg et al. 2010	Apelberg BJ, Onicescu G, Avila-Tang E, Samet JM. 2010. Estimating the risks and benefits of nicotine replacement therapy for smoking cessation in the United States." <i>Am. J. Pub. Health</i> 100(2):341-348.	2.13, 6.4
Arefalk et al. 2011	Arefalk G, Hergens MP, Ingelsson E, Arnlöv J, Michaëlsson K, Lind L, Ye W, Nyrén O, Lambe M, and Sundström J. 2011. Smokeless tobacco (snus) and risk of heart failure: results from two Swedish cohorts. <i>Eur J Prev Cardiol.</i> 19:1120-1127.	2.8
Ashley et al. 2010	Ashley DL, O'Connor RJ, Bernert JT, Watson CH, Polzin GM, Jain RB, Hammond D, Hatsukami DK, Giovino GA, Cummings KM, McNeill A, Shahab L, King B, Fong GT, Zhang L, Xia Y, Yan X, and McCraw JM. 2010. Effect of differing levels of tobacco-specific nitrosamines in cigarette smoke on the levels of biomarkers in smokers. <i>Cancer Epidemiol. Biomarkers Prev.</i> 19:1389-1398.	2, 6.1.2
Asplund 2003	Asplund K. 2003. Smokeless tobacco and cardiovascular disease. <i>Prog Cardiovasc Dis.</i> 45:383-394.	6.0-6.1.1 6.1.2
Auferheide and Gressmann 2008	Auferheide A and Gressmann H. 2008. Mutagenicity of native cigarette mainstream smoke and its gas/vapour phase by use of different tester strains and cigarettes in a modified Ames assay. <i>Mutation Research</i> 656:82-87.	6.1.3
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6.5.4 Index of other references and supporting documents

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1973 Endangered Species Act	U.S. Fish & Wildlife Service. 1973. Endangered Species Act of 1973.	5
2014 municipal solid waste summary tables	Advancing Sustainable Materials Management: 2014 Tables and Figures. Assessing Trends in Material Generation, Recycling, Composting, Combustion with Energy Recovery and Landfilling in the United States. November 2016.	5
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21 CFR 25.40	Title 21 — Food and Drugs; Chapter I — Food and Drug Administration, Department of Health and Human Services. Subchapter A — General. Part 25 — Environmental Impact Considerations.	2.5, 5
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40 CFR § 1502.17	Regulations for Implementing the Procedural Provisions of the National Environmental Policy Act. 2005.	5
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NCI 2016	National Cancer Institute. 2001. Smokeless tobacco and cancer.	2.8
NCSU 2015	North Carolina State University. 2015. Smokeless Tobacco Reference Products.	6.1.3
Niaura 2016	Niaura R. 2016. Re-thinking nicotine and its effects. Schroeder Institute for Tobacco Research and Policy Studies.	2.9

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NTP 2014	National Toxicology Program. 2014. Report on Carcinogens, Thirteenth Edition. Tobacco-Related Exposures. 2014;1-6.	6.1.2
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OECD 1997	OECD Guideline for Testing of Chemicals: Bacteria Reverse Mutation Test adopted July 21, 1997.	6.1.3
Peeler 1996	Peeler CL. 1996. Cigarette testing and the Federal Trade Commission: a historical overview, The FTC Cigarette Test Method for Determining Tar, Nicotine, and Carbon Monoxide Yields of US Cigarettes: report of the NCI Expert Committee (Smoking and Tobacco Control Monograph no. 7). NIH publication no. 96-4028. Bethesda (Maryland): U.S. Department of Health and Human Services, NIH, National Cancer Institute.	6.1.5
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Safety Reporting Portal	FDA Safety Reporting Portal for Tobacco Products. 2016.	9
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TPSAC Meeting, April 10, 2015	Tobacco Products Scientific Advisory Committee. April 10, 2015. U.S. Food and Drug Administration, Tobacco Products Scientific Advisory Committee. Meeting on modified risk tobacco product marketing applications filed by Swedish Match North America [Transcript]. Silver Spring, MD.	3.3, 4
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U.S. EPA Facility Release Report 2015	U.S. EPA Facility Release Report 2015.	5
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USDHHS 2014	U.S. Department of Health and Human Services. 2014. The Health Consequences of Smoking: 50 Years of Progress. A Report of the Surgeon General. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health.	2.5, 2.8, 2.9, 2.11, 2.12, 6.1, 6.1.1, 6.1.4, 6.1.6, 6.2, 6.3
USDHHS 2016	U.S. Department of Health and Human Services. 2016. E-Cigarette Use Among Youth and Young Adults. A Report of the Surgeon General. Rockville, MD.	2.9
WHO 2005	World Health Organization. 2005. Tumours of the oral cavity and oropharynx, In: World Health Organization Classification of Tumours: Pathology and Genetics: Head and Neck Tumours (Barnes, L, Eveson, JW, Reichart, P, & Sidransky, D, eds.) Lyon, France: IARC Press, pp. 163-208.	6.1.1
WHO 2008	World Health Organization Study Group on Tobacco Product Regulation. 2008. The Scientific Basis of Tobacco Product Regulation. Geneva: World Health Organization, WHO Technical Report Series, No. 951.	2.5, 6.1.3
WHO surveillance	World Health Organization. Health topics: Public health surveillance.	9