

Section	Description	Location
<b>1</b>	<b>Cover Letter</b>	<a href="#">1-Cover Letter\cover-letter.pdf</a>
<b>2</b>	<b>Table of Contents, Glossary, and Summary</b>	
2.1	Table of Contents	
2.2	Glossary and Abbreviations	<a href="#">2-TOC and Summary\2-2-Glossary\2-2-glossary-and-abbrev.pdf.pdf</a>
2.3	Executive Summary	<a href="#">2-TOC and Summary\2-3-Exec Summary\2-3-executive-summary.pdf</a>
	Appendix 2.3-1: FDA Grandfather Letter (November 1, 2012)	<a href="#">2-TOC and Summary\2-3-Exec Summary\app-2-3-1-fda-grandfather-ltr.pdf</a>
	Appendix 2.3-2: USSTC Historical Shipment Data (1985 – 2016)	<a href="#">2-TOC and Summary\2-3-Exec Summary\app-2-3-2-usstc-shipmnt-data.xlsx</a>
	Appendix 2.3-3: First Amendment Reservation of Rights	<a href="#">2-TOC and Summary\2-3-Exec Summary\app-2-3-3-first-amend-reserv-rights.pdf</a>
	Appendix 2.3-4: Analyses of HINTS Data (HINTS Public Use File 2016)	<a href="#">2-TOC and Summary\2-3-Exec Summary\app-2-3-4-analyses-of-hints-data.pdf</a>
<b>3</b>	<b>Descriptive Information</b>	
3.1	Description Of Tobacco Product (Formulation, Manufacturing, Packaging, Stability)	<a href="#">3-Descriptive Info\3-1-Descr of Tobacco Prod and Formulation\3-1-description-of-tobacco-product.pdf</a>
	Appendix 3.1-1: ST-IR-003-004; Product Integrity Review and Toxicological Evaluation Guideline, Smokeless Tobacco Products: Test Articles, Prototypes, and Products	<a href="#">3-Descriptive Info\3-1-Descr of Tobacco Prod and Formulation\app-3-1-1-st-ir-003-004.pdf</a>
	Appendix 3.1-2: ST-IR-003-003; Product Integrity Toxicological Evaluation Framework Overview	<a href="#">3-Descriptive Info\3-1-Descr of Tobacco Prod and Formulation\app-3-1-2-st-ir-003-003.pdf</a>
	Appendix 3.1-3: LF-IR-008-005; ALCS Internal Reference Document - USDA Expanded List Maximum Allowable Levels (MALs) and Additional Crop Protection Agents (CPAs) Guidance Residue Levels (GRLs)	<a href="#">3-Descriptive Info\3-1-Descr of Tobacco Prod and Formulation\app-3-1-3-lf-ir-008-005.pdf</a>
	Appendix 3.1-4: CORESTA N° 1 - The Concept and Implementation of CPA Guidance Residue Levels	<a href="#">3-Descriptive Info\3-1-Descr of Tobacco Prod and Formulation\app-3-1-4-coresta-cpa-grls.pdf</a>
	Appendix 3.1-5: ST-TM-235-104; Determination of (b) (4) Components by Near-Infrared	<a href="#">3-Descriptive Info\3-1-Descr of Tobacco Prod and Formulation\app-3-1-5-st-tm-235-104.pdf</a>
	Appendix 3.1-6: ST-TM-235-104; Determination of (b) (4) Components by Near-Infrared Revision History	<a href="#">3-Descriptive Info\3-1-Descr of Tobacco Prod and Formulation\app-3-1-6-st-tm-235-104-rev-history.pdf</a>
	Appendix 3.1-7: ST-TM-410-314; Rapid Determination of pH in Smokeless Tobacco	<a href="#">3-Descriptive Info\3-1-Descr of Tobacco Prod and Formulation\app-3-1-7-st-tm-410-314.pdf</a>

Section	Description	Location
	Appendix 3.1-8: ST-TM-410-314; Rapid Determination of pH in Smokeless Tobacco Revision History	<a href="#">3-Descriptive Info\3-1-Descr of Tobacco Prod and Formulation\app-3-1-8-st-tm-410-314-rev-history.pdf</a>
	Appendix 3.1-9: ST-TM-410-334; Determination of pH in Smokeless Tobacco	<a href="#">3-Descriptive Info\3-1-Descr of Tobacco Prod and Formulation\app-3-1-9-st-tm-410-334.pdf</a>
	Appendix 3.1-10: ST-TM-410-334; Determination of pH in Smokeless Tobacco Revision History	<a href="#">3-Descriptive Info\3-1-Descr of Tobacco Prod and Formulation\app-3-1-10-st-tm-410-334-rev-history.pdf</a>
	Appendix 3.1-11: ST-TM-410-634; Determination of Flavors in Smokeless Tobacco by GC-MS Analytical Method	<a href="#">3-Descriptive Info\3-1-Descr of Tobacco Prod and Formulation\app-3-1-11-st-tm-410-634.pdf</a>
	Appendix 3.1-12: ST-TM-410-634; Determination of Flavors in Smokeless Tobacco by GC-MS Revision History	<a href="#">3-Descriptive Info\3-1-Descr of Tobacco Prod and Formulation\app-3-1-12-st-tm-410-634-rev-history.pdf</a>
	Appendix 3.1-13: ST-TM-440-254; Determination of Volatiles in Smokeless Tobacco by Mechanical Convection Oven	<a href="#">3-Descriptive Info\3-1-Descr of Tobacco Prod and Formulation\app-3-1-13-st-tm-440-254.pdf</a>
	Appendix 3.1-14: ST-TM-440-254; Determination of Volatiles in Smokeless Tobacco by Mechanical Convection Oven Revision History	<a href="#">3-Descriptive Info\3-1-Descr of Tobacco Prod and Formulation\app-3-1-14-st-tm-440-254-rev-history.pdf</a>
	Appendix 3.1-15: ST-TM-440-264; Determination of Oven Volatiles in Smokeless Tobacco by Microwave Moisture Analyzer	<a href="#">3-Descriptive Info\3-1-Descr of Tobacco Prod and Formulation\app-3-1-15-st-tm-440-264.pdf</a>
	Appendix 3.1-16: ST-TM-440-264; Determination of Oven Volatiles in Smokeless Tobacco by Microwave Moisture Analyzer Revision History	<a href="#">3-Descriptive Info\3-1-Descr of Tobacco Prod and Formulation\app-3-1-16-st-tm-440-264-rev-history.pdf</a>
	Appendix 3.1-17: ST-TM-950-104; Quantitation of Tobacco Specific Bacteria	<a href="#">3-Descriptive Info\3-1-Descr of Tobacco Prod and Formulation\app-3-1-17-st-tm-950-104.pdf</a>
	Appendix 3.1-18: ST-TM-950-104; Quantitation of Tobacco Specific Bacteria Revision History	<a href="#">3-Descriptive Info\3-1-Descr of Tobacco Prod and Formulation\app-3-1-18-st-tm-950-104-rev-history.pdf</a>
	Appendix 3.1-19: Sensory Stability of the Candidate Product	<a href="#">3-Descriptive Info\3-1-Descr of Tobacco Prod and Formulation\app-3-1-19-sensory-stability.pdf</a>
	Appendix 3.1-20: Copenhagen® Snuff Fine Cut Total Aerobic Microbial Count and Total Yeast and Mold Count	<a href="#">3-Descriptive Info\3-1-Descr of Tobacco Prod and Formulation\app-3-1-20-micro-tamc-tymc-rpt.pdf</a>
	Appendix 3.1-21: Report on Copenhagen® Snuff Fine Cut - Viability of Select Pathogens in Select Finished Product During Storage at Retail Conditions	<a href="#">3-Descriptive Info\3-1-Descr of Tobacco Prod and Formulation\app-3-1-21-micro-challenge-study.pdf</a>

Section	Description	Location
3.2	Description of Conditions for Use and Actual Use of the Candidate Product	<a href="#">3-Descriptive Info\3-2-Desc of Conditions for Use and Actual Use of Prod\3-2-conditions-for-use-and-actual-use.pdf</a>
	Appendix 3.2-1: ALCS Analyses of PATH Data (PATH Public Use File 2013 – 2014)	<a href="#">3-Descriptive Info\3-2-Desc of Conditions for Use and Actual Use of Prod\app-3-2-1-analyses-of-path-data.pdf</a>
	Appendix 3.2-2: ALCS Analyses of NSDUH Data (NSDUH Public Use File 2014)	<a href="#">3-Descriptive Info\3-2-Desc of Conditions for Use and Actual Use of Prod\app-3-2-2-analyses-of-nsduh-data.pdf</a>
	Appendix 3.2-3: Analyses of ALCS Consumer Behavior Study	<a href="#">3-Descriptive Info\3-2-Desc of Conditions for Use and Actual Use of Prod\app-3-2-3-analyses-of-alcs-constr-behav.pdf</a>
	Appendix 3.2-4: Analyses of ALCS Tracking Study	<a href="#">3-Descriptive Info\3-2-Desc of Conditions for Use and Actual Use of Prod\app-3-2-4-analyses-of-alcs-track-study.pdf</a>
<b>4</b>	<b>Labels, Labeling, and Advertising</b>	
4.1	Labels, Labeling and Advertising	<a href="#">4-Labeling and Advertising\4-1-Labels and Advertising\4-1-labels-labeling-advertising.pdf</a>
	Appendix 4.1-1: Print Advertisement	<a href="#">4-Labeling and Advertising\4-1-Labels and Advertising\app-4-1-1-print-ad.pdf</a>
	Appendix 4.1-2: Direct Mail Front	<a href="#">4-Labeling and Advertising\4-1-Labels and Advertising\app-4-1-2-direct-mail-front.pdf</a>
	Appendix 4.1-3: Direct Mail Back	<a href="#">4-Labeling and Advertising\4-1-Labels and Advertising\app-4-1-3-direct-mail-back.pdf</a>
	Appendix 4.1-4: Email	<a href="#">4-Labeling and Advertising\4-1-Labels and Advertising\app-4-1-4-email.pdf</a>
	Appendix 4.1-5: Website Popup	<a href="#">4-Labeling and Advertising\4-1-Labels and Advertising\app-4-1-5-website-popup.pdf</a>
	Appendix 4.1-6: Promotional Card Exterior	<a href="#">4-Labeling and Advertising\4-1-Labels and Advertising\app-4-1-6-promo-card-exterior.pdf</a>
	Appendix 4.1-7: Promotional Card Interior	<a href="#">4-Labeling and Advertising\4-1-Labels and Advertising\app-4-1-7-promo-card-interior.pdf</a>
	Appendix 4.1-8: Bottom Can Label	<a href="#">4-Labeling and Advertising\4-1-Labels and Advertising\app-4-1-8-bottom-can.pdf</a>
	Appendix 4.1-9: Point Of Sale	<a href="#">4-Labeling and Advertising\4-1-Labels and Advertising\app-4-1-9-point-of-sale.pdf</a>
<b>5</b>	<b>Environmental Assessment</b>	
5.1	Section 5.1 Environmental Assessment Report – Appendix Listing	<a href="#">5-Environmental Assessment\5-1-Environ Assess Rpt\5-1-environ-assess-cover-sheet.pdf</a>
	Appendix 5.1-1: Environmental Assessment: Modified Risk Tobacco Product Application for the Grandfathered Product Copenhagen® Snuff Fine Cut (GF1200194)	<a href="#">5-Environmental Assessment\5-1-Environ Assess Rpt\app-5-1-1-ea-rpt.pdf</a>

	Appendix 5.1-2: Data Summary List for the Product Currently Identified as Copenhagen® Snuff Fine Cut	<a href="#">5-Environmental Assessment\5-1-Environ Assess Rpt\app-5-1-2-ea-data-summ-list.pdf</a>
	Appendix 5.1-3: FDA Citations for the Product Currently Identified as Copenhagen® Snuff Fine Cut	<a href="#">5-Environmental Assessment\5-1-Environ Assess Rpt\app-5-1-3-ea-fda-citations.pdf</a>
<b>6</b>	<b>Summary of All Research Findings</b>	<a href="#">6-Summary of Research Findings\6-1-Health Risks of the Tobacco Prod\6-0-summ-of-all-research-findings.pdf</a>
6.1	Health Risks of the Tobacco Product	<a href="#">6-Summary of Research Findings\6-1-Health Risks of the Tobacco Prod\6-1-health-risks-of-the-tobacco-prod.pdf</a>
6.2	Effect of Marketing On Consumer Understanding And Perceptions	<a href="#">6-Summary of Research Findings\6-2-Effect on Consumer Understanding and Perceptions\6-2-risk-perceptions.pdf</a>
6.3	Effect of the Product on Tobacco Use Behavior Among Current Tobacco Users	<a href="#">6-Summary of Research Findings\6-3-Effect of the Prod on Tobacco Use Behavior-Current Users\6-3-effect-on-behav-current-users.pdf</a>
6.4	Effect On Tobacco Use Initiation Among Nonusers	<a href="#">6-Summary of Research Findings\6-4-Effect on Tobacco Use Initiation-Non-Users\6-4-effect-tobacco-use-init-nonusers.pdf</a>
	Appendix 6.4-1: ALCS Analyses of PATH Data (PATH Public Use File 2013 – 2014)	<a href="#">6-Summary of Research Findings\6-4-Effect on Tobacco Use Initiation-Non-Users\app-6-4-1-analyses-of-path-data.pdf</a>
	Appendix 6.4-2: ALCS Analyses of NSDUH Data (NSDUH Public Use File 2002 – 2015)	<a href="#">6-Summary of Research Findings\6-4-Effect on Tobacco Use Initiation-Non-Users\app-6-4-2-analyses-of-nsduh-data.pdf</a>
6.5	Population Model Research Summary	<a href="#">6-Summary of Research Findings\6-5-Population Model Research Summ\6-5-pop-model-research-summ.pdf</a>
<b>7</b>	<b>Scientific Studies &amp; Analysis</b>	
7.1	Product Analysis – Harmful And Potentially Harmful Constituents (HPHC)	<a href="#">7-Scientific Studies and Analysis\7-1-Prod Analysis-Harmful Constituents\7-1-product-analysis-hphc.pdf</a>
	Appendix 7.1-1: ALCS 095-3370 Determination of pH by the CDC Method	<a href="#">7-Scientific Studies and Analysis\7-1-Prod Analysis-Harmful Constituents\app-7-1-1-alcs-095-3370.pdf</a>
	Appendix 7.1-2: ALCS 095-3371 Determination of Total Moisture by CDC Method	<a href="#">7-Scientific Studies and Analysis\7-1-Prod Analysis-Harmful Constituents\app-7-1-2-alcs-095-3371.pdf</a>
	Appendix 7.1-3: ALCS 095-5020 Determination of Select Carbonyls in Tobacco by UPLC-MSMS	<a href="#">7-Scientific Studies and Analysis\7-1-Prod Analysis-Harmful Constituents\app-7-1-3-alcs-095-5020.pdf</a>
	Appendix 7.1-4: ALCS 095-5021 Determination of BaP in Tobacco Products by GC-MS	<a href="#">7-Scientific Studies and Analysis\7-1-Prod Analysis-Harmful Constituents\app-7-1-4-alcs-095-5021.pdf</a>

Section	Description	Location
	Appendix 7.1-5: ALCS 095-5507 Analysis of Cadmium and Arsenic in Tobacco by ICP-MS	<a href="#">7-Scientific Studies and Analysis\7-1-Prod Analysis-Harmful Constituents\app-7-1-5-alcs-095-5507.pdf</a>
	Appendix 7.1-6: ALCS 095-5519 Determination of TSNAs in Tobacco	<a href="#">7-Scientific Studies and Analysis\7-1-Prod Analysis-Harmful Constituents\app-7-1-6-alcs-095-5519.pdf</a>
	Appendix 7.1-7: ALCS 095-5529 Determination of Nicotine in Tobacco and Tobacco Products by GC Analysis	<a href="#">7-Scientific Studies and Analysis\7-1-Prod Analysis-Harmful Constituents\app-7-1-7-alcs-095-5529.pdf</a>
	Appendix 7.1-8: ISO 17025 Scope Accreditation – 0660-01 170324	<a href="#">7-Scientific Studies and Analysis\7-1-Prod Analysis-Harmful Constituents\app-7-1-8-iso-iec-accred-0660-01-20170324.pdf</a>
	Appendix 7.1-9: ISO 17025 Scope Accreditation – 0660-01 170414	<a href="#">7-Scientific Studies and Analysis\7-1-Prod Analysis-Harmful Constituents\app-7-1-9-iso-iec-accred-0660-01-20170414.pdf</a>
	Appendix 7.1-10: ISO 17025 Scope Accreditation – 0660-01 170421	<a href="#">7-Scientific Studies and Analysis\7-1-Prod Analysis-Harmful Constituents\app-7-1-10-iso-iec-accred-0660-01-20170421.pdf</a>
	Appendix 7.1-11: ALCS Memorandum, “Measurement Uncertainty Data for Smokeless Tobacco Methods” (September 14, 2017)	<a href="#">7-Scientific Studies and Analysis\7-1-Prod Analysis-Harmful Constituents\app-7-1-11-internal-alcs-memo-20170914.pdf</a>
7.2	Product Analysis – Stability	<a href="#">7-Scientific Studies and Analysis\7-2-Non-Clin Studies-Stability Study Brief\7-2-product-analysis-stability.pdf</a>
	Appendix 7.2-1: FDA Guidance for Industry Q1A(R2) Stability (November 2003)	<a href="#">7-Scientific Studies and Analysis\7-2-Non-Clin Studies-Stability Study Brief\app-7-2-1-fda-guidance-q1a-r2-stab-testing.pdf</a>
	Appendix 7.2-2: ALCS 096-3841 pH Analysis of Tobacco – Lancaster	<a href="#">7-Scientific Studies and Analysis\7-2-Non-Clin Studies-Stability Study Brief\app-7-2-2-alcs-096-3841.pdf</a>
	Appendix 7.2-3: ALCS 095-5014 Determination of Nitrite and Nitrate in Smokeless Tobacco Products by IC	<a href="#">7-Scientific Studies and Analysis\7-2-Non-Clin Studies-Stability Study Brief\app-7-2-3-alcs-095-5014.pdf</a>
	Appendix 7.2-4: ALCS Comment Letter to FDA RE: Draft Guidance on Reporting Harmful and Potentially Harmful Constituents (June 1, 2012)	<a href="#">7-Scientific Studies and Analysis\7-2-Non-Clin Studies-Stability Study Brief\app-7-2-4-alcs-comment-letter-20120601.pdf</a>
	Appendix 7.2-5: ALCS 095-3330 Determination of Oven Volatiles, Precision Oven	<a href="#">7-Scientific Studies and Analysis\7-2-Non-Clin Studies-Stability Study Brief\app-7-2-5-alcs-095-3330.pdf</a>
	Appendix 7.2-6: ALCS 095-5519 Determination of TSNAs in Tobacco	<a href="#">7-Scientific Studies and Analysis\7-2-Non-Clin Studies-Stability Study Brief\app-7-2-6-alcs-095-5519.pdf</a>
	Appendix 7.2-7: ALCS 095-3021 Measurement of Water Activity in Tobacco and Tobacco Products	<a href="#">7-Scientific Studies and Analysis\7-2-Non-Clin Studies-Stability Study Brief\app-7-2-7-alcs-095-3021.pdf</a>

Section	Description	Location
7.3	Human Studies	
7.3.1	Appendix 7.3.1-1: PK Study with Subjective Effects	<a href="#">7-Scientific Studies and Analysis\7-3-Human Studies\7-3-1-PK Study\CA21981\alcs-ra-17-02-mst-1-15-rpt-body.pdf</a>
	Appendix 7.3.1-2: ALCS-RA-17-02-MST Factory Release	<a href="#">7-Scientific Studies and Analysis\7-3-Human Studies\7-3-1-PK Study\app-7-3-1-2-alcs-ra-17-02-mst-fact-release.pdf</a>
	Appendix 7.3.1-3: ALCS-RA-17-02-MST Laboratory Report	<a href="#">7-Scientific Studies and Analysis\7-3-Human Studies\7-3-1-PK Study\app-7-3-1-3-alcs-ra-17-02-mst-lab-rpt.pdf</a>
7.3.2	Section 7.3.2: Claim Comprehension and Intentions (CCI) Study	<a href="#">7-Scientific Studies and Analysis\7-3-Human Studies\7-3-2-CS-03-CCI Study Brief\7-3-2-cci-study.pdf</a>
	Appendix 7.3.2-1: CCI Study Report	<a href="#">7-Scientific Studies and Analysis\7-3-Human Studies\7-3-2-CS-03-CCI Study Brief\app-7-3-2-1-ccis-report.pdf</a>
	Appendix 7.3.2-2: CCI Study IRB Exemption Letter	<a href="#">7-Scientific Studies and Analysis\7-3-Human Studies\7-3-2-CS-03-CCI Study Brief\app-7-3-2-2-ccis-irb-exempt-letter.pdf</a>
	Appendix 7.3.2-3: CCI Study Weighting Efficiency File	<a href="#">7-Scientific Studies and Analysis\7-3-Human Studies\7-3-2-CS-03-CCI Study Brief\app-7-3-2-3-ccis-weighting-efficiency.pdf</a>
	Appendix 7.3.2-4: CCI Study Tests of Normality	<a href="#">7-Scientific Studies and Analysis\7-3-Human Studies\7-3-2-CS-03-CCI Study Brief\app-7-3-2-4-ccis-tests-of-normality.xlsx</a>
	Appendix 7.3.2-5: CCI Study Frequency Distributions	<a href="#">7-Scientific Studies and Analysis\7-3-Human Studies\7-3-2-CS-03-CCI Study Brief\app-7-3-2-5-ccis-freq-distrib.xlsx</a>
	Appendix 7.3.2-6: CCI Study Protocol	<a href="#">7-Scientific Studies and Analysis\7-3-Human Studies\7-3-2-CS-03-CCI Study Brief\app-7-3-2-6-ccis-protocol.pdf</a>
	Appendix 7.3.2-7: CCI Study Report Signature Page	<a href="#">7-Scientific Studies and Analysis\7-3-Human Studies\7-3-2-CS-03-CCI Study Brief\app-7-3-2-7-ccis-final-rpt-sign-page.pdf</a>
	Appendix 7.3.2-8: CCI Study Final Data	<a href="#">7-Scientific Studies and Analysis\7-3-Human Studies\7-3-2-CS-03-CCI Study Brief\app-7-3-2-8-ccis-final-data.xpt</a>
	Appendix 7.3.2-9: CCI Study Additional Analysis	<a href="#">7-Scientific Studies and Analysis\7-3-Human Studies\7-3-2-CS-03-CCI Study Brief\app-7-3-2-9-ccis-addtl-analys.pdf</a>
	Appendix 7.3.2-10: CCI Study Item Tracking Matrix	<a href="#">7-Scientific Studies and Analysis\7-3-Human Studies\7-3-2-CS-03-CCI Study Brief\app-7-3-2-10-ccis-item-track-matrix.xlsx</a>



Section	Description	Location
	Appendix 7.3.2-11: CCI Study Codebook	<a href="#">7-Scientific Studies and Analysis\7-3-Human Studies\7-3-2-CS-03-CCI Study Brief\app-7-3-2-11-ccis-codebook.pdf</a>
	Appendix 7.3.2-12: CCI Study SAP	<a href="#">7-Scientific Studies and Analysis\7-3-Human Studies\7-3-2-CS-03-CCI Study Brief\app-7-3-2-12-ccis-sap.pdf</a>
	Appendix 7.3.2-13: CCI Study Survey / Questionnaire	<a href="#">7-Scientific Studies and Analysis\7-3-Human Studies\7-3-2-CS-03-CCI Study Brief\app-7-3-2-13-ccis-quest.pdf</a>
	Appendix 7.3.2-14: CCI Study SAP Signature Page	<a href="#">7-Scientific Studies and Analysis\7-3-Human Studies\7-3-2-CS-03-CCI Study Brief\app-7-3-2-14-ccis-sap-sign-page.pdf</a>
	Appendix 7.3.2-15: CCI Study SSAP Syntax Code	<a href="#">7-Scientific Studies and Analysis\7-3-Human Studies\7-3-2-CS-03-CCI Study Brief\app-7-3-2-15-ccis-ssap-syntax-code.pdf</a>
7.3.3	Analysis of Previous Studies	<a href="#">7-Scientific Studies and Analysis\7-3-Human Studies\7-3-3-Analysis of Prev Studies\7-3-3-analysis-of-prev-studies.pdf</a>
	Appendix 7.3.3-1: CS01 Claims Qualitative Study	<a href="#">7-Scientific Studies and Analysis\7-3-Human Studies\7-3-3-Analysis of Prev Studies\app-7-3-3-1-cs-01-claims-qual-study.pdf</a>
	Appendix 7.3.3-2: CS01.1 Claims Qualitative Study	<a href="#">7-Scientific Studies and Analysis\7-3-Human Studies\7-3-3-Analysis of Prev Studies\app-7-3-3-2-cs-01-1-claims-qual-study.pdf</a>
	Appendix 7.3.3-3: Perception and Behavioral Intentions (PBI) Validation Study – Debriefing Statements for Phases I and II	<a href="#">7-Scientific Studies and Analysis\7-3-Human Studies\7-3-3-Analysis of Prev Studies\app-7-3-3-3-pbi-val-study-debrief.pdf</a>
	Appendix 7.3.3-4: PBI Validation Study – Prescreener	<a href="#">7-Scientific Studies and Analysis\7-3-Human Studies\7-3-3-Analysis of Prev Studies\app-7-3-3-4-pbi-val-study-prescreen.pdf</a>
	Appendix 7.3.3-5: PBI Validation Study – Informed Consent for Phase I	<a href="#">7-Scientific Studies and Analysis\7-3-Human Studies\7-3-3-Analysis of Prev Studies\app-7-3-3-5-pbi-val-study-icf-phase-1.pdf</a>
	Appendix 7.3.3-6: PBI Validation Study – Informed Consent for Phase II	<a href="#">7-Scientific Studies and Analysis\7-3-Human Studies\7-3-3-Analysis of Prev Studies\app-7-3-3-6-pbi-val-study-icf-phase-2.pdf</a>
	Appendix 7.3.3-7: PBI Validation Study – Protocol	<a href="#">7-Scientific Studies and Analysis\7-3-Human Studies\7-3-3-Analysis of Prev Studies\app-7-3-3-7-pbi-val-study-protocol.pdf</a>
	Appendix 7.3.3-8: PBI Validation Study – Report	<a href="#">7-Scientific Studies and Analysis\7-3-Human Studies\7-3-3-Analysis of Prev Studies\app-7-3-3-8-pbi-val-study-final-rpt.pdf</a>

Section	Description	Location
	Appendix 7.3.3-9: PBI Validation Study – IRB Protocol Exemption	<a href="#">7-Scientific Studies and Analysis\7-3-Human Studies\7-3-3-Analysis of Prev Studies\app-7-3-3-9-pbi-irb-protocol-exempt.pdf</a>
	Appendix 7.3.3-10: SAP for PBI Validation Study (Sep 2016)	<a href="#">7-Scientific Studies and Analysis\7-3-Human Studies\7-3-3-Analysis of Prev Studies\app-7-3-3-10-pbi-val-study-sap-sep2016.pdf</a>
	Appendix 7.3.3-11: SAP for PBI Validation Study (Mar 2017)	<a href="#">7-Scientific Studies and Analysis\7-3-Human Studies\7-3-3-Analysis of Prev Studies\app-7-3-3-11-pbi-val-study-sap-mar2017.pdf</a>
7.4	Secondary Data Analyses and Computational Models	
7.4.1	Linked Mortality Analysis – Appendix Listing	<a href="#">7-Scientific Studies and Analysis\7-4-Secondary Data Analyses and Models\7-4-1-Linked Mortality Analyses\7-4-1-linked-mortality-analysis.pdf</a>
	Appendix 7.4.1-1: Linked Mortality Analysis – Exclusive Chew and Snuff	<a href="#">7-Scientific Studies and Analysis\7-4-Secondary Data Analyses and Models\7-4-1-Linked Mortality Analyses\app-7-4-1-1-lma-excl-chew-and-snuff.xlsx</a>
	Appendix 7.4.1-2: Linked Mortality Analysis – SLT Results	<a href="#">7-Scientific Studies and Analysis\7-4-Secondary Data Analyses and Models\7-4-1-Linked Mortality Analyses\app-7-4-1-2-lma-slt-results.xlsx</a>
	Appendix 7.4.1-3: Smokeless Tobacco Mortality Risks: Analyses of Two Contemporary Nationally Representative Longitudinal Mortality Studies	<a href="#">7-Scientific Studies and Analysis\7-4-Secondary Data Analyses and Models\7-4-1-Linked Mortality Analyses\app-7-4-1-3-slt-mortality-risks.pdf</a>
	Appendix 7.4.1-4.: Linked Mortality Analysis Data and SAS Code	<a href="#">7-Scientific Studies and Analysis\7-4-Secondary Data Analyses and Models\7-4-1-Linked Mortality Analyses\app-7-4-1-4-lma-data-and-sas.pdf</a>
7.4.2	Population Model	<a href="#">7-Scientific Studies and Analysis\7-4-Secondary Data Analyses and Models\7-4-2-Population Model Dev\7-4-2-population-model.pdf</a>
	Appendix 7.4.2-1: Population Model – Tables	<a href="#">7-Scientific Studies and Analysis\7-4-Secondary Data Analyses and Models\7-4-2-Population Model Dev\app-7-4-2-1-pop-model-tables.pdf</a>
	Appendix 7.4.2-2: Population Model – Computer Code	<a href="#">7-Scientific Studies and Analysis\7-4-Secondary Data Analyses and Models\7-4-2-Population Model Dev\app-7-4-2-2-pop-model-comp-code.pdf</a>
	Appendix 7.4.2-3: Population Model – Rare Events, False Positive Paradox, Small Samples, and Superpopulation Concept	<a href="#">7-Scientific Studies and Analysis\7-4-Secondary Data Analyses and Models\7-4-2-Population Model Dev\app-7-4-2-3-pop-model-rare-events.pdf</a>
	Appendix 7.4.2-4: Population Model - Analysis of Input Data from the Claim Comprehension and Intentions (CCI) Study for Modified Case in the ALCS Cohort Model	<a href="#">7-Scientific Studies and Analysis\7-4-Secondary Data Analyses and Models\7-4-2-Population Model Dev\app-7-4-2-4-pop-model-input-data-ccis.pdf</a>



Section	Description	Location
7.4.3	Adverse Event Summary	<a href="#">7-Scientific Studies and Analysis\7-4-Secondary Data Analyses and Models\7-4-3-AE Report\7-4-3-adverse-event-summary.pdf</a>
	Appendix 7.4.3-1: Adverse Event Survey Questions (August 24, 2017)	<a href="#">7-Scientific Studies and Analysis\7-4-Secondary Data Analyses and Models\7-4-3-AE Report\app-7-4-3-1-ae-survey-questions.pdf</a>
7.4.4	Centers for Disease Control and Prevention (CDC) Data – Appendix Listing	<a href="#">7-Scientific Studies and Analysis\7-4-Secondary Data Analyses and Models\7-4-4-USSTC CDC Data\7-4-4-cdc-data.pdf</a>
	Appendix 7.4.4-1: Copenhagen Fine Cut Data Tables and Charts	<a href="#">7-Scientific Studies and Analysis\7-4-Secondary Data Analyses and Models\7-4-4-USSTC CDC Data\app-7-4-4-1-cfc-data-tables-charts.xlsx</a>
7.5	Summary of the Literature	
7.5.1	Literature Selection and Review	<a href="#">7-Scientific Studies and Analysis\7-5-Summary of Literature\7-5-1-Lit Selection and Review\7-5-1-lit-selection-and-review.pdf</a>
7.5.2-1	Initial Users' Behavior	<a href="#">7-Scientific Studies and Analysis\7-5-Summary of Literature\7-5-2-Users Behavior Lit Summ\7-5-2-1-init-users-behav-lit-summ.pdf</a>
7.5.2-2	Update Users' Behavior	<a href="#">7-Scientific Studies and Analysis\7-5-Summary of Literature\7-5-2-Users Behavior Lit Summ\7-5-2-2-updt-users-behav-lit-summ.pdf</a>
7.5.3-1	Initial Nonusers' Behavior	<a href="#">7-Scientific Studies and Analysis\7-5-Summary of Literature\7-5-3-Nonusers Behavior Lit Summ\7-5-3-1-init-nonusers-behav-lit-summ.pdf</a>
7.5.3-2	Update Nonusers' Behavior	<a href="#">7-Scientific Studies and Analysis\7-5-Summary of Literature\7-5-3-Nonusers Behavior Lit Summ\7-5-3-2-updt-nonusers-behav-lit-summ.pdf</a>
7.5.4-1	Initial Chemistry and Constituents	<a href="#">7-Scientific Studies and Analysis\7-5-Summary of Literature\7-5-4-Chem Lit Summ Scenarios\7-5-4-1-init-chem-lit-summ.pdf</a>
7.5.4-2	Update Chemistry and Constituents	<a href="#">7-Scientific Studies and Analysis\7-5-Summary of Literature\7-5-4-Chem Lit Summ Scenarios\7-5-4-2-updt-chem-lit-summ.pdf</a>
7.5.5-1	Initial Exposure	<a href="#">7-Scientific Studies and Analysis\7-5-Summary of Literature\7-5-5-Exposure Lit Summ\7-5-5-1-init-exposure-lit-summ.pdf</a>
7.5.5-2	Update Exposure	<a href="#">7-Scientific Studies and Analysis\7-5-Summary of Literature\7-5-5-Exposure Lit Summ\7-5-5-2-updt-exposure-lit-summ.pdf</a>
7.5.6-1	Initial Health Risks	<a href="#">7-Scientific Studies and Analysis\7-5-Summary of Literature\7-5-6-Health Risks Lit Summ\7-5-6-1-init-health-risks-lit-summ.pdf</a>

<b>Section</b>	<b>Description</b>	<b>Location</b>
7.5.6-2	Update Health Risks	<a href="#">7-Scientific Studies and Analysis\7-5-Summary of Literature\7-5-6-Health Risks Lit Summ\7-5-6-2-updt-health-risks-lit-summ.pdf</a>
7.5.7-1	Initial Perceptions	<a href="#">7-Scientific Studies and Analysis\7-5-Summary of Literature\7-5-7-Perceptions Lit Summ\7-5-7-1-init-perceptions-lit-summ.pdf</a>
7.5.7-2	Update Perceptions	<a href="#">7-Scientific Studies and Analysis\7-5-Summary of Literature\7-5-7-Perceptions Lit Summ\7-5-7-2-updt-perceptions-lit-summ.pdf</a>
7.5.8-1	Initial Topography	<a href="#">7-Scientific Studies and Analysis\7-5-Summary of Literature\7-5-8-Topography Lit Summ\7-5-8-1-init-topog-lit-summ.pdf</a>
7.5.8-2	Update Topography	<a href="#">7-Scientific Studies and Analysis\7-5-Summary of Literature\7-5-8-Topography Lit Summ\7-5-8-2-updt-topog-lit-summ.pdf</a>
<b>8</b>	<b>Postmarket Surveillance</b>	
8.1	Postmarket Assessment Plan	<a href="#">8-PostMarketing Surveillance\8-1-Postmarket Assess Plan\8-1-postmarket-assessment-plan.pdf</a>