



# **General Snus<sup>®</sup> Patterns of Use Study**

## **Wave 4 Technical Report – Final**

Swedish Match North America Protocol Number: SMU 19-01 GENS

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SIGNATURES OF RESPONSIBLE PARTIES

SWEDISH MATCH NORTH AMERICA

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## EXECUTIVE SUMMARY

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(b) (4), (b) (6)

**Responsibility**

Principal Investigator

Research Director

Research Advisor

Medical Writer

Statistics Advisor

Data Analysis

Statistics Advisor

Data Analysis

Document Management

Quality Assurance

Engagement Services

Research Operations

Research Advisor

Client Partner

DOCUMENT HISTORY

Document Version	Document Status	Version Date	Reason for and Description of Change	Changed By
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## LIST OF ABBREVIATIONS

Abbreviation	Definition
FDA	FDA Food and Drug Administration
MRTP	Modified Risk Tobacco Product
MRTPA	Modified Risk Tobacco Product Application
(b) (4)	
(b) (4)	
PMTA	Premarket Tobacco Product Application
SAP	Statistical Analysis Plan
SMNA	Swedish Match North America, LLC
(b) (4)	
U.S.	United States



## 1. BACKGROUND & RATIONALE

In November 2015, Swedish Match USA, Inc. (SMU) received market authorization for *General Snus*®, a moist tobacco product placed under the upper lip that does not involve spitting or chewing. In its first applications reviewed through the MRTP pathway, the FDA deferred final action on providing *General Snus*® a MRTP designation, providing guidance on how SMU could amend their application to provide greater support for a modified risk designation. SMU filed its amended MRTPA on 17 September 2018, and the FDA granted the risk modification order on 22 October 2019. The *General Snus*® Patterns of Use Study (the study) is for post-marketing surveillance reporting following the granted risk modification order.

## 2. STUDY OBJECTIVES

The overarching research questions for this study were the following:

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### 2.1 PRIMARY OBJECTIVES

The primary objectives of the study were the following:

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## 2.2 SECONDARY OBJECTIVES

The secondary objectives of the study were the following:

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## 3. OVERVIEW OF RESEARCH METHODS

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Full details of all research methods and study procedures can be found in the *General Snus®* Patterns of Use Study – Study Protocol.

### 3.1 INCLUSION CRITERIA

Respondents had to meet each of the following criteria to be included in the study:

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### 3.2 EXCLUSION CRITERIA

Respondents who met of the following criteria were excluded from the study:

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#### 4. OVERVIEW OF ANALYSIS METHODS

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## 5. WAVE 4 FIELDING SUMMARY

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## 6. WAVE 4 STUDY RESULTS

### 6.1 DEMOGRAPHIC CHARACTERISTICS OF RESPONDENTS AT WAVE 4

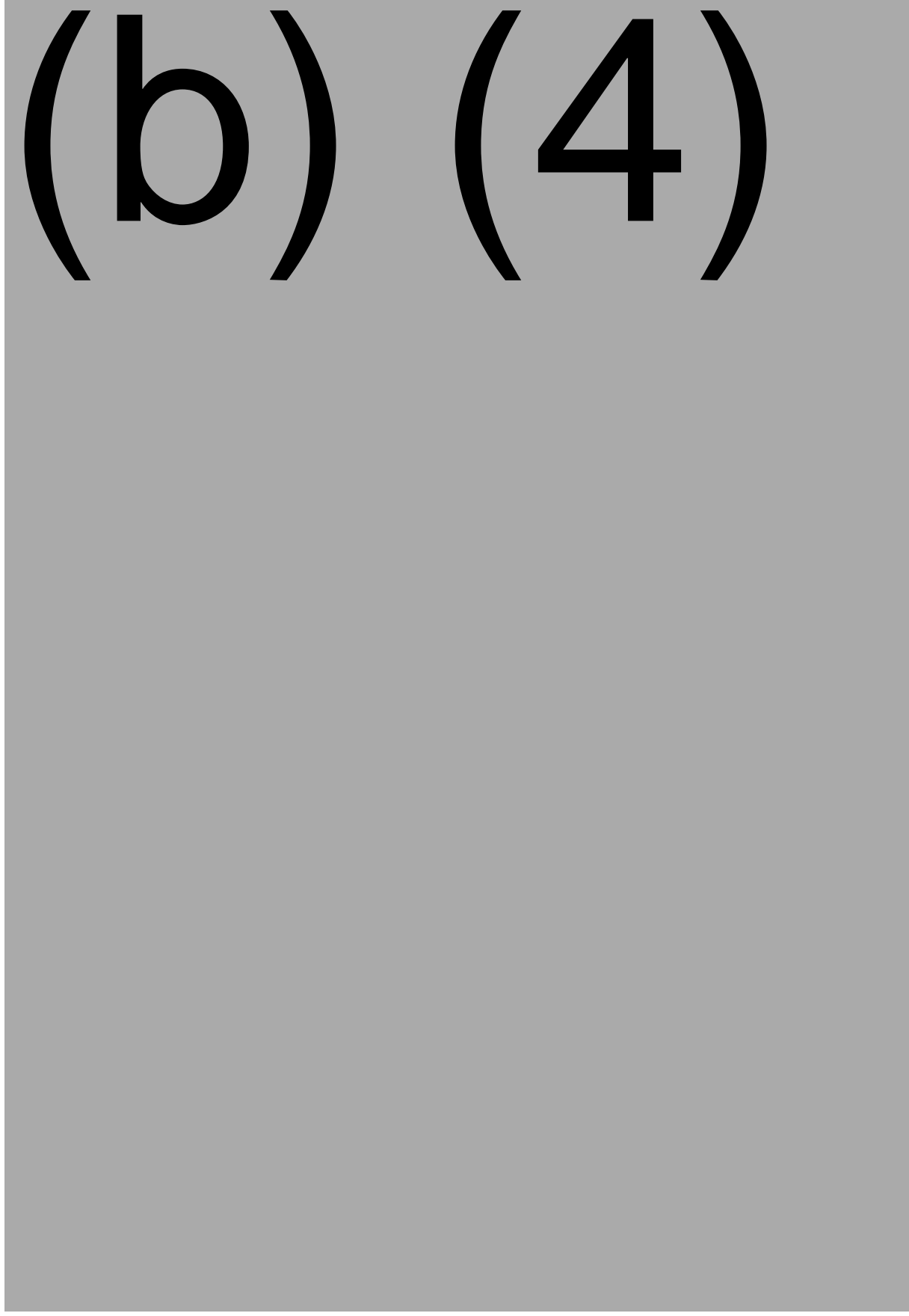
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## 6.2 WAVE 4 RESULTS FOR PRIMARY OBJECTIVES

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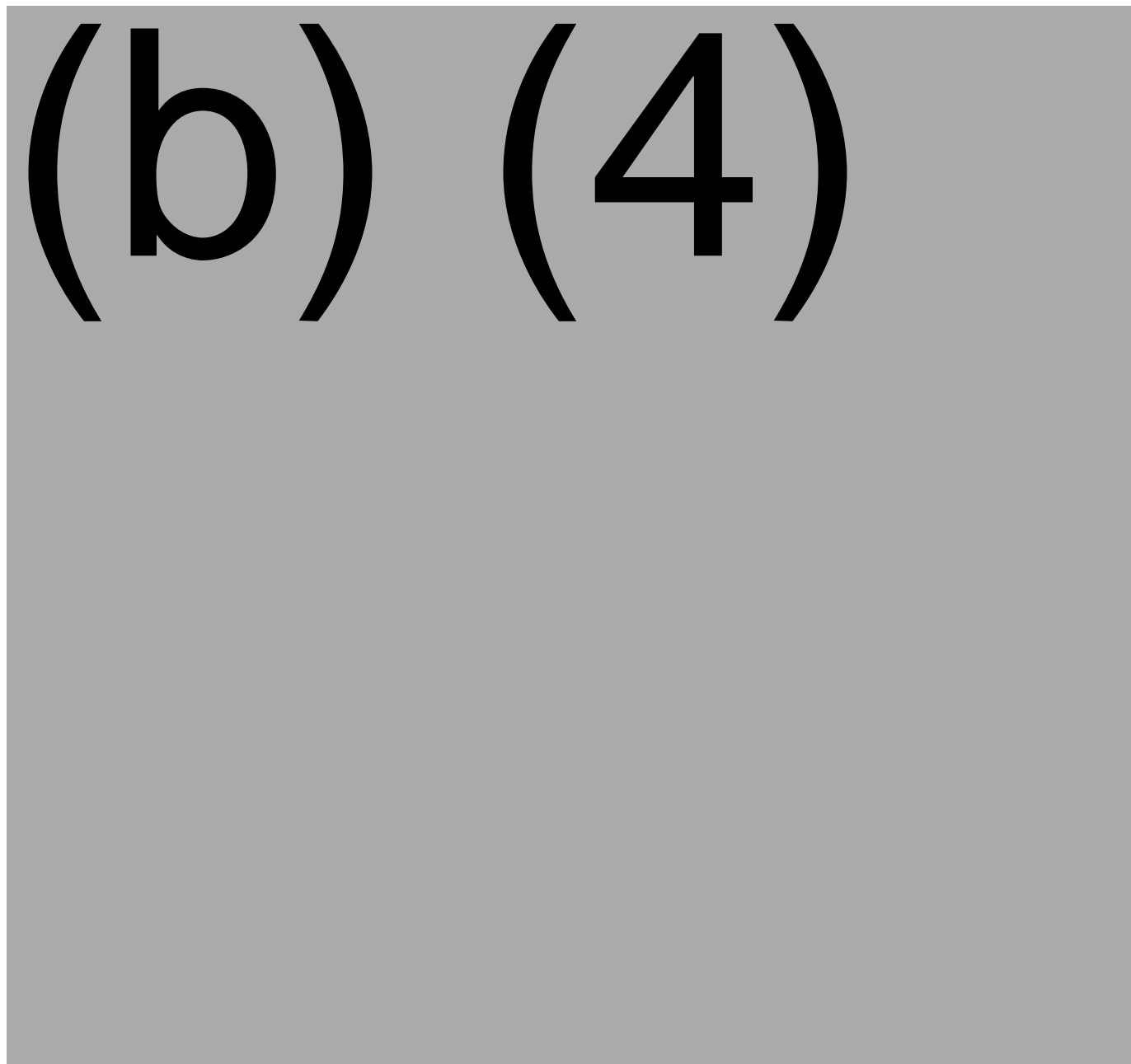
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## 7. SUMMARY OF WAVE 4 RESULTS

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Certificate Of Completion

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Envelope Originator:

Certificate Pages: 5

Initials: 0

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Signature ID:	Resent: 08-Nov-2022   18:32
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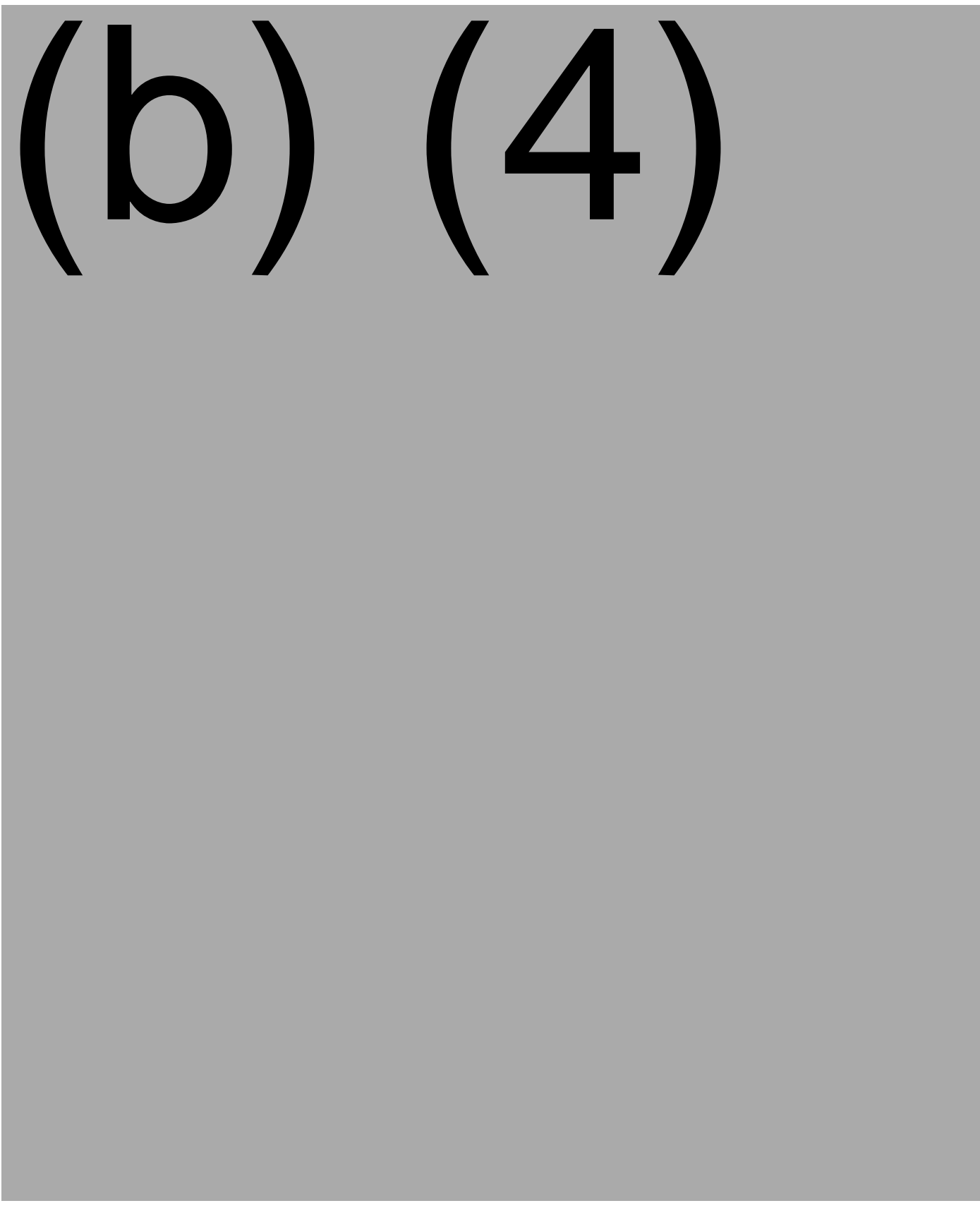
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