

16.1.2 Sample Case Report Form

SWEDISH MATCH AB		Subject Number: _____
Protocol Number: SM 08-01	Investigator: _____	Subject Initials: ____. ____.
Covance Study Number: 7694-105	Site: _____	

RDC CASE REPORT FORM

A CONTROLLED STUDY OF THE ABILITY OF A TRADITIONAL SWEDISH SMOKELESS TOBACCO PRODUCT ("SNUS") TO INCREASE THE QUIT RATE AMONG CIGARETTE SMOKERS WHO WISH TO STOP SMOKING

Protocol No. SM 08-01
Covance Study No. 7694-105

for

SWEDISH MATCH AB
ROSENLUNDSGATAN 36
SE-118 85 STOCKHOLM
SWEDEN

by

Covance Clinical Research Unit Inc.
3402 Kinsman Blvd
Madison, Wisconsin 53704

SWEDISH MATCH AB		Subject Number: _____
Protocol Number: SM 08-01	Investigator: _____	Subject Initials: ____. ____.
Covance Study Number: 7694-105	Site: _____	

INCLUSION CRITERIA

Subjects who meet the following criteria may be included in the study. Did the subject meet the following criteria requirements for inclusion? (✓ Yes or No)		Yes 1	No* 2
01	The subject is male or female, between 25 and 65 years of age, inclusive. If female, the subject has a negative urine pregnancy test and is not lactating, or has not been of childbearing potential for at least 3 months prior to use of study product. To be considered to be not of childbearing potential, the subject must be postmenopausal for at least 2 years; have had a hysterectomy or bilateral tubal ligation, or be proven to be otherwise incapable of pregnancy. If of childbearing potential, the subject must have been practicing one of the following methods of contraception consistently for at least 1 month prior to study entry and agree to continue practicing it during the study: hormonal contraceptives, intrauterine device, spermicide and barrier, spouse/partner sterility; or is practicing abstinence and agrees to continue abstinence or to start an acceptable method of contraception from the above list if sexual activity commences.		
02	The subject smokes > 9 cigarettes per day (average daily consumption during past month).		
03	The subject has smoked daily for > 1 year.		
04	The subject is motivated to quit smoking with the help of a smokeless tobacco alternative.		
05	The subject is in good general health as evidenced by medical history, physical examination, routine blood chemistry (Hb, total WBC, transaminases, creatinine, electrolytes) , and an ECG		
06	The subject practices, by self-report, good oral hygiene (including brushing teeth at least twice per day and having regular dental check-ups).		
07	The subject is able and willing to provide written informed consent.		
08	The subject agrees to comply with the requirements of the protocol and complete study measures.		
09	The subject has stable residence and telephone.		

*If No, document on Subject Eligibility Page.

SWEDISH MATCH AB		Subject Number: _____
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Covance Study Number: 7694-105	Site: _____	

EXCLUSION CRITERIA

The following will exclude potential subjects from the study. Does the subject have any of the following? (✓ Yes or No)	Yes* 1	No 2
01 The subject is a current user of ST (defined as daily usage during more than 1 week within past 6 months) or is unable to refrain from NRT or any other non-protocol treatment during the study. Use of pipes, cigars, cigarillos, snuff, and chewing tobacco is also prohibited during the study.		
02 The subject is a female who is pregnant or lactating.		
03 The subject has oral conditions that could potentially be made worse by use of study product, for instance, exposed dental services in the upper sulcus.		
04 The subject has used any type of pharmaceutical (including some psychotropics, e.g., wellbutrin) or other products for smoking cessation within the past 3 months.		
05 The subject has a history of clinically significant renal, hepatic, neurological, or chronic pulmonary disease that in the judgment of the investigator precludes participation.		
06 The subject has a history of cardiovascular disease, including myocardial infarction within the last 3 months, significant cardiac arrhythmias, or poorly controlled hypertension (defined as a diastolic pressure of more than 90 mm Hg or a systolic pressure of more than 140 mm Hg) that in the judgment of the investigator precludes participation.		
07 The subject has a history of alcohol or substance abuse or dependence other than cigarette smoking within the past year		
08 Use of any illicit drug or smoked marijuana in the last 3 months.		
09 The subject is unwilling to be randomized into active or placebo conditions, or be available for follow-up assessments.		
10 The subject resides in a household where another member is currently participating in the study.		

*If Yes, document on Subject Eligibility Page.

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Covance Study Number: 7694-105	Site: _____	

INFORMATION SESSION

Date of Information Session	Did the subject attend the Information Session?	Comments
____/____/____ DD/MMM/YYYY	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No (explain, if No)	

SUBJECT ELIGIBILITY

Date the Subject Signed the Informed Consent Form: ____/____/____ DD/MMM/YYYY				
Did the subject meet all of the inclusion/exclusion criteria? 1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No				
If the subject did not meet all of the Inclusion/Exclusion criteria, provide criterion number and explanation below.				
Category	Inclusion/Exclusion No.	Explanation	Exemption Granted?	If Yes, Date Granted DD/MMM/YYYY
1 <input type="checkbox"/> Inclusion 2 <input type="checkbox"/> Exclusion			1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No	____/____/____
1 <input type="checkbox"/> Inclusion 2 <input type="checkbox"/> Exclusion			1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No	____/____/____
1 <input type="checkbox"/> Inclusion 2 <input type="checkbox"/> Exclusion			1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No	____/____/____

SWEDISH MATCH AB		Subject Number: _____
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SCREENING

DEMOGRAPHICS

Date DD/MMM/YYYY ____/____/____	Date of Birth DD/MMM/YYYY ____/____/____	Gender 1 <input type="checkbox"/> Male 2 <input type="checkbox"/> Female	Ethnicity 1 <input type="checkbox"/> Hispanic or Latino 2 <input type="checkbox"/> Not Hispanic or Latino
Race			
1 <input type="checkbox"/> White		4 <input type="checkbox"/> Native Hawaiian or Other Pacific Islander	
2 <input type="checkbox"/> Black or African American		5 <input type="checkbox"/> American Indian/Alaskan Native	
3 <input type="checkbox"/> Asian		6 <input type="checkbox"/> Other: _____	

BODY MEASUREMENTS

Were Body Measurements Collected?		Date DD/MMM/YYYY
1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No		____/____/____
Parameter	Unit	Result
Height	in	_____.

SWEDISH MATCH AB		Subject Number: _____
Protocol Number: SM 08-01	Investigator: _____	Subject Initials: ____. ____.
Covance Study Number: 7694-105	Site: _____	

SCREENING

VITAL SIGNS

Were vital signs collected? 1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No	Date DD/MMM/YYYY ____/____/____	Actual Time 24-hour clock ____:____	Was Subject seated for 5 minutes? 1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No
Parameter	Unit	Result	
Systolic Blood Pressure	mmHg	_____	
Diastolic Blood Pressure	mmHg	_____	
Heart Rate	beats/minute	_____	
Respiratory Rate	breaths/minute	_____	
Body Temperature	°C	_____ . _____	
Weight	lb	_____ . _____	

SWEDISH MATCH AB		Subject Number: _____
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Covance Study Number: 7694-105	Site: _____	

SCREENING

LABORATORY EVALUATIONS

Were the scheduled laboratory samples obtained?		Date DD/MMM/YYYY
1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No (Specify samples not done, reason): _____		____/____/____
Evaluation: Safety Urine & Blood Tests; Biomarker Blood Tests		
Requisition Number 1: _____		
Requisition Number 2 (if applicable): _____		
Requisition Number 3 (if applicable): _____		
Were there any clinically significant labs? 1 <input type="checkbox"/> Yes (specify below) 2 <input type="checkbox"/> No		
Requisition Number	Test Name	Test Code ID

Note: Attach copy of signed laboratory report.

URINE PREGNANCY TEST

Result		
1 <input type="checkbox"/> Positive	2 <input type="checkbox"/> Negative	9 <input type="checkbox"/> N/A, Male or Woman of Non-childbearing Potential

URINE DRUG SCREEN

Drug Screen Result*	
1 <input type="checkbox"/> Positive	2 <input type="checkbox"/> Negative

*If result derived from test performed by a clinical laboratory, attach copy of signed laboratory report to the CRF.

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SCREENING

12-LEAD ELECTROCARDIOGRAM REPORT

Was ECG performed?	Was Subject Supine at Least 5 Minutes?	Date DD/MMM/YYYY	Actual Time 24-hour clock
₁ <input type="checkbox"/> Yes ₂ <input type="checkbox"/> No	₁ <input type="checkbox"/> Yes ₂ <input type="checkbox"/> No	____/____/____	____:____
ECG Interpretation: ₁ <input type="checkbox"/> Normal ₂ <input type="checkbox"/> Abnormal, NCS ₃ <input type="checkbox"/> Abnormal, CS			
Comments Regarding CS Findings:			

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Covance Study Number: 7694-105	Site: _____	

SCREENING

MEDICAL HISTORY

Does the subject have any relevant medical history? 1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No	Date DD/MMM/YYYY ___/___/___		
Diagnosis/Procedure	Date of Onset DD/MMM/YYYY	Date of Resolution DD/MMM/YYYY	
1.	___/___/___	___/___/___	9 <input type="checkbox"/> ONGOING
2.	___/___/___	___/___/___	9 <input type="checkbox"/> ONGOING
3.	___/___/___	___/___/___	9 <input type="checkbox"/> ONGOING
4.	___/___/___	___/___/___	9 <input type="checkbox"/> ONGOING
5.	___/___/___	___/___/___	9 <input type="checkbox"/> ONGOING
6.	___/___/___	___/___/___	9 <input type="checkbox"/> ONGOING
7.	___/___/___	___/___/___	9 <input type="checkbox"/> ONGOING
8.	___/___/___	___/___/___	9 <input type="checkbox"/> ONGOING
9.	___/___/___	___/___/___	9 <input type="checkbox"/> ONGOING
10.	___/___/___	___/___/___	9 <input type="checkbox"/> ONGOING
11.	___/___/___	___/___/___	9 <input type="checkbox"/> ONGOING
12.	___/___/___	___/___/___	9 <input type="checkbox"/> ONGOING
13.	___/___/___	___/___/___	9 <input type="checkbox"/> ONGOING
14.	___/___/___	___/___/___	9 <input type="checkbox"/> ONGOING
15.	___/___/___	___/___/___	9 <input type="checkbox"/> ONGOING
Consider the following systems when performing the assessment:			
<ul style="list-style-type: none"> • Skin • Ears, Eyes, Nose, Throat (EENT) • Breasts • Respiratory • Cardiovascular 	<ul style="list-style-type: none"> • Lymphatic/Hematologic • Gastrointestinal • Genitourinary • Musculoskeletal • Endocrine 	<ul style="list-style-type: none"> • Neurological • Immunological • Psychological • Allergies 	

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SCREENING

SMOKING HISTORY

Was Smoking History collected?	Date DD/MMM/YYYY	
₁ <input type="checkbox"/> Yes ₂ <input type="checkbox"/> No	___/___/___	
Parameter	Result	Comments
Age subject began smoking daily	___ ___	
Average number of cigarettes smoked per day over the past year	___ ___	
Has subject used smokeless tobacco in the past?	₁ <input type="checkbox"/> Yes ₂ <input type="checkbox"/> No	
Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? List details of NRT products used in Comments section.	₁ <input type="checkbox"/> Yes ₂ <input type="checkbox"/> No If yes, how many times? ___ ___	
Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? List details of other pharmaceuticals used in the Comments section.	₁ <input type="checkbox"/> Yes ₂ <input type="checkbox"/> No If yes, how many times? ___ ___	
Has the subject attempted to quit with the use of other smoking cessation aids? List details of other smoking cessation aids used in the Comments section.	₁ <input type="checkbox"/> Yes ₂ <input type="checkbox"/> No If yes, how many times? ___ ___	
Has the subject made any other attempts to quit smoking? List details of other quit attempts in the Comments section.	₁ <input type="checkbox"/> Yes ₂ <input type="checkbox"/> No If yes, how many times? ___ ___	

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SCREENING

ORAL HEALTH EXAMINATION

Date DD/MMM/YYYY	Procedure	Findings*	Findings
___/___/___	Evidence of Leukoplakia	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No 9 <input type="checkbox"/> NE	
	Exposed dental cervices in upper sulcus?	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No 9 <input type="checkbox"/> NE	
	Other Oral Keratosis	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No 9 <input type="checkbox"/> NE	

*Indicate NE if system was not examined.

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SCREENING

PHYSICAL EXAMINATIONS

Does the subject have any abnormal findings?	Date DD/MM/YYYY
1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No	___/___/___
Findings	
1.	
2.	
3.	
4.	
5.	
6.	
7.	
8.	
9.	
10.	
11.	
12.	
13.	
14.	
15.	
Consider the following systems when performing the assessment:	
<ul style="list-style-type: none"> ● Oral Cavity ● General Appearance ● Skin ● HEENT 	<ul style="list-style-type: none"> ● Neck (including thyroid) ● Lungs ● Heart ● Abdomen
<ul style="list-style-type: none"> ● Extremities ● Neurologic/Nervous System ● Lymph Nodes 	

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SCREENING

BEHAVIORAL COUNSELING

Date DD/MMM/YYYY	Parameter	Result	Comments
___/___/___	Was Behavioral Counseling Given?	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No	
	Was "Cleaning the Air" booklet provided?	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No	

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BASELINE, WEEK 0

EXPIRED CARBON MONOXIDE

Date DD/MM/YYYY	Actual Time 24-hour clock	ECO Level ppm	%COHb	Comments
___/___/___	___:___	_____	_____.	

BEHAVIORAL COUNSELING

Date DD/MM/YYYY	Parameter	Result	Comments
___/___/___	Was Behavioral Counseling Given?	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No	

QUESTIONNAIRES

Date DD/MM/YYYY	
___/___/___	
Questionnaire	Was Questionnaire Administered?
FTND	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No
MNWS	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No

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BASELINE, WEEK 0

RANDOMIZATION

Date DD/MMM/YYYY ____/____/____	Actual Time 24-hour clock __ : __
Was Subject randomized?	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No

PRODUCT DISPENSATION

Date DD/MMM/YYYY ____/____/____	
Product	Amount Dispensed
0.5 g of snus or matching placebo	____ logs
1.0 g of snus or matching placebo	____ logs

DIARY DISTRIBUTION

Date DD/MMM/YYYY ____/____/____	
Did subject receive diary and usage instructions?	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No

SWEDISH MATCH AB		Subject Number: _____
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**STUDY PRODUCT TEST PERIOD
WEEKS 1 THROUGH 4**

STATUS REVIEW

Date DD/MM/YYYY	Scheduled Timepoint	Parameter	Result	Comments
//____	Week 1	Was Subject contacted by telephone?	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No	
		Was Subject's smoking status reviewed?	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No	
		Was Subject's use of study product reviewed?	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No	
		Approximately how many cigarettes did the subject smoke that week?	_____	
		Was Behavioral Counseling Given?	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No	
//____	Week 2	Was Subject contacted by telephone?	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No	
		Was Subject's smoking status reviewed?	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No	
		Was Subject's use of study product reviewed?	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No	
		Approximately how many cigarettes did the subject smoke that week?	_____	
		Was Behavioral Counseling Given?	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No	
//____	Week 3	Was Subject contacted by telephone?	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No	
		Was Subject's smoking status reviewed?	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No	
		Was Subject's use of study product reviewed?	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No	
		Approximately how many cigarettes did the subject smoke that week?	_____	
		Was Behavioral Counseling Given?	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No	
//____	Week 4	Was Subject contacted by telephone?	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No	
		Was Subject's smoking status reviewed?	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No	
		Was Subject's use of study product reviewed?	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No	
		Approximately how many cigarettes did the subject smoke that week?	_____	
		Was Behavioral Counseling Given?	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No	
		Was Subject reminded about the complete switch from cigarettes no later than the first day of Week 5?	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No	

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**INTERVENTION PHASE
WEEK 6**

STATUS REVIEW

Date DD/MMM/YYYY	Parameter	Result	Comments
___/___/___	Was Subject asked HDYF? question during Week 5?	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No	

VITAL SIGNS

Were vital signs collected?	Date DD/MMM/YYYY	Actual Time 24-hour clock	Was Subject seated for 5 minutes?
1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No	___/___/___	___ : ___	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No
Parameter	Unit	Result	
Systolic Blood Pressure	mmHg	_____	
Diastolic Blood Pressure	mmHg	_____	
Heart Rate	beats/minute	_____	
Respiratory Rate	breaths/minute	_____	
Body Temperature	°C	_____ . _____	
Weight	lb	_____ . _____	

SWEDISH MATCH AB		Subject Number: _____
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**INTERVENTION PHASE
WEEK 6**

LABORATORY EVALUATIONS

Were the scheduled laboratory samples obtained?		Date DD/MMM/YYYY
1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No (Specify samples not done, reason): _____		____/____/____
Evaluation: Biomarker Blood Tests		
Requisition Number 1: _____		
Requisition Number 2 (if applicable): _____		
Requisition Number 3 (if applicable): _____		
Were there any clinically significant labs? 1 <input type="checkbox"/> Yes (specify below) 2 <input type="checkbox"/> No		
Requisition Number	Test Name	Test Code ID

Note: Attach copy of signed laboratory report.

SWEDISH MATCH AB		Subject Number: _____
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**INTERVENTION PHASE
WEEK 6**

EXPIRED CARBON MONOXIDE

Date DD/MMM/YYYY	Actual Time 24-hour clock	ECO Level ppm	%COHb	Comments
___/___/___	___:___	_____	_____.	

BEHAVIORAL COUNSELING

Date DD/MMM/YYYY	Parameter	Result	Comments
___/___/___	Was Behavioral Counseling Given?	₁ <input type="checkbox"/> Yes ₂ <input type="checkbox"/> No	

QUESTIONNAIRES

Date DD/MMM/YYYY	
___/___/___	
Questionnaire	Was Questionnaire Administered?
MNWS	₁ <input type="checkbox"/> Yes ₂ <input type="checkbox"/> No

SWEDISH MATCH AB		Subject Number: _____
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**INTERVENTION PHASE
WEEK 6**

PRODUCT DISPENSATION

Date DD/MMM/YYYY ____/____/____	
Product	Amount Dispensed
0.5 g of snus or matching placebo	____ __ __ logs
1.0 g of snus or matching placebo	____ __ __ logs

STATUS REVIEW

Date DD/MMM/YYYY	Parameter	Result	Comments
____/____/____	Was Subject's smoking status reviewed?	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No	
	Was Subject compliant?	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No	
	If Subject was not compliant, approximately how many cigarettes did the subject smoke that week?	____ __ __	
	Was Subject asked HDYF? question?	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No	

DIARY DISTRIBUTION

Date DD/MMM/YYYY ____/____/____	
Did subject receive diary and usage instructions?	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No

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**INTERVENTION PHASE
WEEK 8**

STATUS REVIEW

Date DD/MM/YYYY	Parameter	Result	Comments
___/___/___	Was Subject contacted by telephone?	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No	
	Was Subject's smoking status reviewed?	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No	
	Was Subject's use of study product reviewed?	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No	
	Was Subject compliant?	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No	
	If Subject was not compliant, approximately how many cigarettes did the subject smoke that week?	_____	
	Was Behavioral Counseling Given?	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No	
	Was Subject asked HDYF? question?	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No	

SWEDISH MATCH AB		Subject Number: _____
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Covance Study Number: 7694-105	Site: _____	

**INTERVENTION PHASE
WEEK 10**

VITAL SIGNS

Were vital signs collected? 1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No	Date DD/MMM/YYYY ____/____/____	Actual Time 24-hour clock __ : __	Was Subject seated for 5 minutes? 1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No
Parameter	Unit	Result	
Systolic Blood Pressure	mmHg	_____	
Diastolic Blood Pressure	mmHg	_____	
Heart Rate	beats/minute	_____	
Respiratory Rate	breaths/minute	_____	
Body Temperature	°C	_____ . _____	
Weight	lb	_____ . _____	

SWEDISH MATCH AB		Subject Number: _____
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**INTERVENTION PHASE
WEEK 10**

EXPIRED CARBON MONOXIDE

Date DD/MMM/YYYY	Actual Time 24-hour clock	ECO Level ppm	%COHb	Comments
___/___/___	___:___	_____	_____.	

BEHAVIORAL COUNSELING

Date DD/MMM/YYYY	Parameter	Result	Comments
___/___/___	Was Behavioral Counseling Given?	₁ <input type="checkbox"/> Yes ₂ <input type="checkbox"/> No	

QUESTIONNAIRES

Date DD/MMM/YYYY	
___/___/___	
Questionnaire	Was Questionnaire Administered?
MNWS	₁ <input type="checkbox"/> Yes ₂ <input type="checkbox"/> No

SWEDISH MATCH AB		Subject Number: _____
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Covance Study Number: 7694-105	Site: _____	

**INTERVENTION PHASE
WEEK 10**

PRODUCT DISPENSATION

Date DD/MMM/YYYY ____/____/____	
Product	Amount Dispensed
0.5 g of snus or matching placebo	____ __ __ logs
1.0 g of snus or matching placebo	____ __ __ logs

STATUS REVIEW

Date DD/MMM/YYYY	Parameter	Result	Comments
____/____/____	Was Subject's smoking status reviewed?	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No	
	Was Subject's use of study product reviewed?	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No	
	Was Subject compliant?	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No	
	If Subject was not compliant, approximately how many cigarettes did the subject smoke that week?	_____	
	Was Subject asked HDYF? question?	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No	

DIARY DISTRIBUTION

Date DD/MMM/YYYY ____/____/____	
Did subject receive diary and usage instructions?	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No

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**INTERVENTION PHASE
WEEK 13**

STATUS REVIEW

Date DD/MM/YYYY	Parameter	Result	Comments
___/___/___	Was Subject contacted by telephone?	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No	
	Was Subject's smoking status reviewed?	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No	
	Was Subject's use of study product reviewed?	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No	
	Was Subject compliant?	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No	
	If Subject was not compliant, approximately how many cigarettes did the subject smoke that week?	_____	
	Was Behavioral Counseling Given?	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No	
	Was Subject asked HDYF? question?	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No	
	Was Subject instructed to cut down on product use during upcoming Weeks 14 – 16 to avoid a too abrupt ending of nicotine uptake?	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No	

SWEDISH MATCH AB		Subject Number: _____
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Covance Study Number: 7694-105	Site: _____	

**INTERVENTION PHASE
WEEK 16**

VITAL SIGNS

Were vital signs collected? 1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No	Date DD/MMM/YYYY ____/____/____	Actual Time 24-hour clock __ : __	Was Subject seated for 5 minutes? 1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No
Parameter	Unit	Result	
Systolic Blood Pressure	mmHg	_____	
Diastolic Blood Pressure	mmHg	_____	
Heart Rate	beats/minute	_____	
Respiratory Rate	breaths/minute	_____	
Body Temperature	°C	_____ . _____	
Weight	lb	_____ . _____	

SWEDISH MATCH AB		Subject Number: _____
Protocol Number: SM 08-01	Investigator: _____	Subject Initials: ____. ____.
Covance Study Number: 7694-105	Site: _____	

**INTERVENTION PHASE
WEEK 16**

LABORATORY EVALUATIONS

Were the scheduled laboratory samples obtained?		Date DD/MMM/YYYY
1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No (Specify samples not done, reason): _____		____/____/____
Evaluation: Biomarker Blood Tests		
Requisition Number 1: _____		
Requisition Number 2 (if applicable): _____		
Requisition Number 3 (if applicable): _____		
Were there any clinically significant labs? 1 <input type="checkbox"/> Yes (specify below) 2 <input type="checkbox"/> No		
Requisition Number	Test Name	Test Code ID

Note: Attach copy of signed laboratory report.

SWEDISH MATCH AB		Subject Number: _____
Protocol Number: SM 08-01	Investigator: _____	Subject Initials: ____. ____.
Covance Study Number: 7694-105	Site: _____	

**INTERVENTION PHASE
WEEK 16**

ORAL HEALTH EXAMINATION

Date DD/MM/YYYY	Procedure	Findings*	Findings
___/___/___	Evidence of Leukoplakia	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No 9 <input type="checkbox"/> NE	
	Exposed dental cervices in upper sulcus?	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No 9 <input type="checkbox"/> NE	
	Other Oral Keratosis	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No 9 <input type="checkbox"/> NE	

*Indicate NE if system was not examined.

SWEDISH MATCH AB		Subject Number: _____
Protocol Number: SM 08-01	Investigator: _____	Subject Initials: ____. ____.
Covance Study Number: 7694-105	Site: _____	

**INTERVENTION PHASE
WEEK 16**

PHYSICAL EXAMINATIONS

Does the subject have any abnormal findings?	Date DD/MM/YYYY
1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No	___/___/___
Findings	
1.	
2.	
3.	
4.	
5.	
6.	
7.	
8.	
9.	
10.	
11.	
12.	
13.	
14.	
15.	
Consider the following systems when performing the assessment:	
<ul style="list-style-type: none"> • Oral Cavity • General Appearance • Skin • HEENT 	<ul style="list-style-type: none"> • Neck (including thyroid) • Lungs • Heart • Abdomen
	<ul style="list-style-type: none"> • Extremities • Neurologic/Nervous System • Lymph Nodes

SWEDISH MATCH AB		Subject Number: _____
Protocol Number: SM 08-01	Investigator: _____	Subject Initials: ____. ____.
Covance Study Number: 7694-105	Site: _____	

**INTERVENTION PHASE
WEEK 16**

EXPIRED CARBON MONOXIDE

Date DD/MMM/YYYY	Actual Time 24-hour clock	ECO Level ppm	%COHb	Comments
___/___/___	___:___	_____	_____.	

BEHAVIORAL COUNSELING

Date DD/MMM/YYYY	Parameter	Result	Comments
___/___/___	Was Behavioral Counseling Given?	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No	

QUESTIONNAIRES

Date DD/MMM/YYYY	
___/___/___	
Questionnaire	Was Questionnaire Administered?
FTND	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No
MNWS	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No

SWEDISH MATCH AB		Subject Number: _____
Protocol Number: SM 08-01	Investigator: _____	Subject Initials: ____. ____.
Covance Study Number: 7694-105	Site: _____	

**INTERVENTION PHASE
WEEK 16**

STATUS REVIEW

Date DD/MM/YYYY	Parameter	Result	Comments
___/___/___	Was Subject's smoking status reviewed?	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No	
	Was Subject's use of study product reviewed?	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No	
	Was Subject compliant?	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No	
	If Subject was not compliant, approximately how many cigarettes did the subject smoke that week?	_____	
	Was Subject asked HDYF? question?	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No	

DIARY DISTRIBUTION

Date DD/MM/YYYY	
___/___/___	
Did subject receive diary and usage instructions?	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No

SWEDISH MATCH AB		Subject Number: _____
Protocol Number: SM 08-01	Investigator: _____	Subject Initials: ____. ____.
Covance Study Number: 7694-105	Site: _____	

**FOLLOW-UP PHASE
WEEKS 20 AND 24**

STATUS REVIEW

Date DD/MM/YYYY	Scheduled Timepoint	Parameter	Result	Comments
___/___/___	Week 20	Was Subject contacted by telephone?	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No	
		Was Subject's smoking status reviewed?	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No	
		Was Subject compliant?	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No	
		If Subject was not compliant, approximately how many cigarettes did the subject smoke that week?	_____	
		Was Behavioral Counseling Given?	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No	
		Was Subject asked HDYF? question?	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No	
___/___/___	Week 24	Was Subject contacted by telephone?	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No	
		Was Subject's smoking status reviewed?	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No	
		Was Subject compliant?	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No	
		If Subject was not compliant, approximately how many cigarettes did the subject smoke that week?	_____	
		Was Behavioral Counseling Given?	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No	
		Was Subject asked HDYF? question?	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No	

SWEDISH MATCH AB		Subject Number: _____
Protocol Number: SM 08-01	Investigator: _____	Subject Initials: ____. ____.
Covance Study Number: 7694-105	Site: _____	

**FOLLOW-UP PHASE
WEEK 28**

VITAL SIGNS

Were vital signs collected? 1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No	Date DD/MMM/YYYY ____/____/____	Actual Time 24-hour clock __ : __	Was Subject seated for 5 minutes? 1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No
Parameter	Unit	Result	
Systolic Blood Pressure	mmHg	_____	
Diastolic Blood Pressure	mmHg	_____	
Heart Rate	beats/minute	_____	
Respiratory Rate	breaths/minute	_____	
Body Temperature	°C	_____ . _____	
Weight	lb	_____ . _____	

SWEDISH MATCH AB		Subject Number: _____
Protocol Number: SM 08-01	Investigator: _____	Subject Initials: ____. ____.
Covance Study Number: 7694-105	Site: _____	

**FOLLOW-UP PHASE
WEEK 28**

LABORATORY EVALUATIONS

Were the scheduled laboratory samples obtained?		Date DD/MMM/YYYY
1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No (Specify samples not done, reason): _____		____/____/____
Evaluation: Biomarker Blood Tests		
Requisition Number 1: _____		
Requisition Number 2 (if applicable): _____		
Requisition Number 3 (if applicable): _____		
Were there any clinically significant labs? 1 <input type="checkbox"/> Yes (specify below) 2 <input type="checkbox"/> No		
Requisition Number	Test Name	Test Code ID

Note: Attach copy of signed laboratory report.

SWEDISH MATCH AB		Subject Number: _____
Protocol Number: SM 08-01	Investigator: _____	Subject Initials: ____. ____.
Covance Study Number: 7694-105	Site: _____	

**FOLLOW-UP PHASE
WEEK 28**

ORAL HEALTH EXAMINATION

Date DD/MMM/YYYY	Procedure	Findings*	Findings
___/___/___	Evidence of Leukoplakia	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No 9 <input type="checkbox"/> NE	
	Exposed dental cervices in upper sulcus?	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No 9 <input type="checkbox"/> NE	
	Other Oral Keratosis	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No 9 <input type="checkbox"/> NE	

*Indicate NE if system was not examined.

SWEDISH MATCH AB		Subject Number: _____
Protocol Number: SM 08-01	Investigator: _____	Subject Initials: ____. ____.
Covance Study Number: 7694-105	Site: _____	

**FOLLOW-UP PHASE
WEEK 28**

PHYSICAL EXAMINATIONS

Does the subject have any abnormal findings?	Date DD/MM/YYYY
1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No	___/___/___
Findings	
1.	
2.	
3.	
4.	
5.	
6.	
7.	
8.	
9.	
10.	
11.	
12.	
13.	
14.	
15.	
Consider the following systems when performing the assessment:	
<ul style="list-style-type: none"> • Oral Cavity • General Appearance • Skin • HEENT 	<ul style="list-style-type: none"> • Neck (including thyroid) • Lungs • Heart • Abdomen
	<ul style="list-style-type: none"> • Extremities • Neurologic/Nervous System • Lymph Nodes

SWEDISH MATCH AB		Subject Number: _____
Protocol Number: SM 08-01	Investigator: _____	Subject Initials: ____. ____.
Covance Study Number: 7694-105	Site: _____	

**FOLLOW-UP PHASE
WEEK 28**

EXPIRED CARBON MONOXIDE

Date DD/MMM/YYYY	Actual Time 24-hour clock	ECO Level ppm	%COHb	Comments
___/___/___	___:___	_____	_____.	

BEHAVIORAL COUNSELING

Date DD/MMM/YYYY	Parameter	Result	Comments
___/___/___	Was Behavioral Counseling Given?	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No	

QUESTIONNAIRES

Date DD/MMM/YYYY	
___/___/___	
Questionnaire	Was Questionnaire Administered?
FTND	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No
MNWS	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No

SWEDISH MATCH AB		Subject Number: _____
Protocol Number: SM 08-01	Investigator: _____	Subject Initials: ____. ____.
Covance Study Number: 7694-105	Site: _____	

**FOLLOW-UP PHASE
WEEK 28**

STATUS REVIEW

Date DD/MM/YYYY	Parameter	Result	Comments
___/___/___	Was Subject's smoking status reviewed?	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No	
	Was Subject compliant?	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No	
	If Subject was not compliant, approximately how many cigarettes did the subject smoke that week?	_____	
	Was Subject asked HDYF? question?	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No	

SWEDISH MATCH AB		Subject Number: _____
Protocol Number: SM 08-01	Investigator: _____	Subject Initials: ____. ____.
Covance Study Number: 7694-105	Site: _____	

PREVIOUS AND CONCOMITANT MEDICATIONS

Has the subject taken any medications prior to the first dose and/or during the study as restricted by the protocol?

1 Yes, list below. 2 No

Drug Name:		
Indication:		
Dose:		
Unit: Select only one 1 <input type="checkbox"/> grams 2 <input type="checkbox"/> micrograms 3 <input type="checkbox"/> milligrams 4 <input type="checkbox"/> milliliter 5 <input type="checkbox"/> tablet 6 <input type="checkbox"/> other	Frequency: Select only one 1 <input type="checkbox"/> one time 2 <input type="checkbox"/> whenever necessary 3 <input type="checkbox"/> every morning 4 <input type="checkbox"/> at bedtime 5 <input type="checkbox"/> every day 6 <input type="checkbox"/> twice daily	7 <input type="checkbox"/> three times daily 8 <input type="checkbox"/> four times daily 10 <input type="checkbox"/> every four hours 11 <input type="checkbox"/> every other day 12 <input type="checkbox"/> every week 13 <input type="checkbox"/> other, specify
Start Date¹ <small>DD/MMM/YYYY</small> ____/____/____	Stop Date¹ <small>DD/MMM/YYYY</small> ____/____/____ 9 <input type="checkbox"/> ONGOING	
Drug Name:		
Indication:		
Dose:		
Unit: Select only one 1 <input type="checkbox"/> grams 2 <input type="checkbox"/> micrograms 3 <input type="checkbox"/> milligrams 4 <input type="checkbox"/> milliliter 5 <input type="checkbox"/> tablet	Frequency: Select only one 1 <input type="checkbox"/> one time 2 <input type="checkbox"/> whenever necessary 3 <input type="checkbox"/> every morning 4 <input type="checkbox"/> at bedtime 5 <input type="checkbox"/> every day 6 <input type="checkbox"/> twice daily	7 <input type="checkbox"/> three times daily 8 <input type="checkbox"/> four times daily 10 <input type="checkbox"/> every four hours 11 <input type="checkbox"/> every other day 12 <input type="checkbox"/> every week 13 <input type="checkbox"/> other, specify
Start Date¹ <small>DD/MMM/YYYY</small> ____/____/____	Stop Date¹ <small>DD/MMM/YYYY</small> ____/____/____ 9 <input type="checkbox"/> ONGOING	
*START AND STOP DATE: If medication is given on a regular schedule, report start date only once. If dose regimen changes, report as a new line of information. Report start and stop dates for each change in dose regimen		

SWEDISH MATCH AB		Subject Number: _____
Protocol Number: SM 08-01	Investigator: _____	Subject Initials: ____. ____.
Covance Study Number: 7694-105	Site: _____	

ADVERSE EVENTS

Did the subject experience any adverse events? 1 Yes, list below. 2 No

Adverse Event: 			
Onset Date DD/MMM/YYYY	Onset Time 24-hour clock	Resolved Date DD/MMM/YYYY	Resolved Time 24-hour clock
___/___/___	___:___	___/___/___	___:___
9 <input type="checkbox"/> ONGOING			
Serious Event: Select only one	Severity: Select only one	Relationship to Product: Select only one	
1 <input type="checkbox"/> Yes	1 <input type="checkbox"/> Mild	1 <input type="checkbox"/> Not Related	
2 <input type="checkbox"/> No	2 <input type="checkbox"/> Moderate	2 <input type="checkbox"/> Unlikely	
	3 <input type="checkbox"/> Severe	3 <input type="checkbox"/> Possibly Related	
		4 <input type="checkbox"/> Probably Related	
		5 <input type="checkbox"/> Definitely Related	
Action Taken: Select only one		Outcome to Date: Select only one	
1 <input type="checkbox"/> None		1 <input type="checkbox"/> Recovered	
2 <input type="checkbox"/> Other Drug Therapy, Specify as Con. Med.		2 <input type="checkbox"/> Continuing without Treatment	
3 <input type="checkbox"/> Other Treatment or Procedure, Specify: _____		3 <input type="checkbox"/> Continuing with Treatment	
4 <input type="checkbox"/> Discontinuation of Drug Therapy		4 <input type="checkbox"/> Death	
5 <input type="checkbox"/> Discontinuation from Study			

SWEDISH MATCH AB		Subject Number: _____
Protocol Number: SM 08-01	Investigator: _____	Subject Initials: ____. ____.
Covance Study Number: 7694-105	Site: _____	

ADDITIONAL ASSESSMENTS - 12-LEAD ELECTROCARDIOGRAM REPORT

Were any additional 12-lead ECGs collected? 1 Yes, list below. 2 No

Date DD/MM/YYYY	Actual Time 24-hour clock	ECG Interpretation:	Comments Regarding CS Findings
___/___/___	___:___	1 <input type="checkbox"/> Normal 2 <input type="checkbox"/> Abnormal, NCS 3 <input type="checkbox"/> Abnormal, CS	
___/___/___	___:___	1 <input type="checkbox"/> Normal 2 <input type="checkbox"/> Abnormal, NCS 3 <input type="checkbox"/> Abnormal, CS	
___/___/___	___:___	1 <input type="checkbox"/> Normal 2 <input type="checkbox"/> Abnormal, NCS 3 <input type="checkbox"/> Abnormal, CS	
___/___/___	___:___	1 <input type="checkbox"/> Normal 2 <input type="checkbox"/> Abnormal, NCS 3 <input type="checkbox"/> Abnormal, CS	

SWEDISH MATCH AB	Subject Number: _____
Protocol Number: SM 08-01	Investigator: _____
Covance Study Number: 7694-105	Site: _____
	Subject Initials: ____. _____. ____.

ADDITIONAL ASSESSMENTS - VITAL SIGNS

Were any additional vital signs collected? 1 Yes, list below. 2 No

Date DD/MM/YYYY	Actual Time 24-hour clock	Position	Parameter	Unit	Result
____/____/____	____ : ____	1 <input type="checkbox"/> Standing 2 <input type="checkbox"/> Supine 3 <input type="checkbox"/> Seated 4 <input type="checkbox"/> Other, Specify: _____	Systolic Blood Pressure	mmHg	_____
			Diastolic Blood Pressure	mmHg	_____
			Heart Rate	beats/minute	_____
			Respiratory Rate	breaths/minute	_____
			Body Temperature	°C	_____
			Comments:		
____/____/____	____ : ____	1 <input type="checkbox"/> Standing 2 <input type="checkbox"/> Supine 3 <input type="checkbox"/> Seated 4 <input type="checkbox"/> Other, Specify: _____	Systolic Blood Pressure	mmHg	_____
			Diastolic Blood Pressure	mmHg	_____
			Heart Rate	beats/minute	_____
			Respiratory Rate	breaths/minute	_____
			Body Temperature	°C	_____
			Comments:		
____/____/____	____ : ____	1 <input type="checkbox"/> Standing 2 <input type="checkbox"/> Supine 3 <input type="checkbox"/> Seated 4 <input type="checkbox"/> Other, Specify: _____	Systolic Blood Pressure	mmHg	_____
			Diastolic Blood Pressure	mmHg	_____
			Heart Rate	beats/minute	_____
			Respiratory Rate	breaths/minute	_____
			Body Temperature	°C	_____
			Comments:		

SWEDISH MATCH AB		Subject Number: _____
Protocol Number: SM 08-01	Investigator: _____	Subject Initials: ____. ____.
Covance Study Number: 7694-105	Site: _____	

ADDITIONAL ASSESSMENTS - PHYSICAL EXAMINATIONS

Does the subject have any abnormal findings?	Date DD/MM/YYYY
1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No	____/____/____
Findings	
1.	
2.	
3.	
4.	
5.	
6.	
7.	
8.	
9.	
10.	
11.	
12.	
13.	
14.	
15.	
Consider the following systems when performing the assessment:	
<ul style="list-style-type: none"> ● Oral Cavity ● General Appearance ● Skin ● HEENT 	<ul style="list-style-type: none"> ● Neck (including thyroid) ● Lungs ● Heart ● Abdomen
<ul style="list-style-type: none"> ● Extremities ● Neurologic/Nervous System ● Lymph Nodes 	

SWEDISH MATCH AB		Subject Number: _____
Protocol Number: SM 08-01	Investigator: _____	Subject Initials: ____. ____.
Covance Study Number: 7694-105	Site: _____	

ORAL HEALTH EXAMINATION

Date DD/MM/YYYY	Procedure	Findings*	Findings
___/___/___	Evidence of Leukoplakia	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No 9 <input type="checkbox"/> NE	
	Exposed dental cervices in upper sulcus?	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No 9 <input type="checkbox"/> NE	
	Other Oral Keratosis	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No 9 <input type="checkbox"/> NE	
___/___/___	Evidence of Leukoplakia	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No 9 <input type="checkbox"/> NE	
	Exposed dental cervices in upper sulcus?	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No 9 <input type="checkbox"/> NE	
	Other Oral Keratosis	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No 9 <input type="checkbox"/> NE	
___/___/___	Evidence of Leukoplakia	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No 9 <input type="checkbox"/> NE	
	Exposed dental cervices in upper sulcus?	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No 9 <input type="checkbox"/> NE	
	Other Oral Keratosis	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No 9 <input type="checkbox"/> NE	

*Indicate NE if system was not examined.

SWEDISH MATCH AB		Subject Number: _____
Protocol Number: SM 08-01	Investigator: _____	Subject Initials: ____. ____.
Covance Study Number: 7694-105	Site: _____	____. ____.

STUDY COMPLETION

Date the subject completed OR withdrew from the study: ____/____/____
DD/MMM/YYYY

Reason for Withdrawal (check one):

99 NA, Completed Study

1 Adverse Event, specify: _____

2 Terminated by Sponsor

3 Consent Withdrawn

4 Lost to Follow-up

9 Other, specify: _____

Investigator Comments (if none, leave blank): _____

I have reviewed the data in this case report and found them to be complete and accurate.
 (To be signed and dated after the subject has ended participation in the study.)

 Principal Investigator

 Date
DD/MMM/YYYY

Blank Case Report Form for Study: E7694105D

Book: CRF

Initials:

Subject #:

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion:

1. I have not smoked any cigarettes at all during the past week (1 or 2 puffs = 1 cigarette)

Correct Incorrect

2. I have smoked on average cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify:

4. Did you use smokeless tobacco products, nicotine-containing products (e.g., gum or patch), or other smoking cessation products this week?

Yes No

If yes, what type (smokeless tobacco, pharmaceutical nicotine replacement products [gum / patch / other], other nicotine products [e.g., lozenges])?

5. I have consumed on average the following number of snus sachets per day:

Sachet Size:

Large (1g)

Small (0.5g)

6. I have experienced the following Adverse Events:

7. I think the Adverse Event is related to the snus product:

Correct

Incorrect

Don't Know

I have not experienced an Adverse Event

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Page Version No. WEEK_1 (v1, 25-MAR-2009)

Document Number

Initials:

Subject #:

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion:

1. I have not smoked any cigarettes at all during the past week (1 or 2 puffs = 1 cigarette)

Correct Incorrect

2. I have smoked on average cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify:

4. Did you use smokeless tobacco products, nicotine-containing products (e.g., gum or patch), or other smoking cessation products this week?

Yes No

If yes, what type (smokeless tobacco, pharmaceutical nicotine replacement products [gum / patch / other], other nicotine products [e.g., lozenges])?

5. I have consumed on average the following number of snus sachets per day:

Sachet Size:

Large (1g)

Small (0.5g)

6. I have experienced the following Adverse Events:

7. I think the Adverse Event is related to the snus product:

Correct

Incorrect

Don't Know

I have not experienced an Adverse Event

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Page Version No. WEEK_2 (v1, 25-MAR-2009)

Document Number

Initials:

Subject #:

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion:

1. I have not smoked any cigarettes at all during the past week (1 or 2 puffs = 1 cigarette)

Correct Incorrect

2. I have smoked on average cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify:

4. Did you use smokeless tobacco products, nicotine-containing products (e.g., gum or patch), or other smoking cessation products this week?

Yes No

If yes, what type (smokeless tobacco, pharmaceutical nicotine replacement products [gum / patch / other], other nicotine products [e.g., lozenges])?

5. I have consumed on average the following number of snus sachets per day:

Sachet Size:

Large (1g)

Small (0.5g)

6. I have experienced the following Adverse Events:

7. I think the Adverse Event is related to the snus product:

Correct

Incorrect

Don't Know

I have not experienced an Adverse Event

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Page Version No. WEEK_3 (v1, 25-MAR-2009)

Document Number

Initials:

Subject #:

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion:

1. I have not smoked any cigarettes at all during the past week (1 or 2 puffs = 1 cigarette)

Correct Incorrect

2. I have smoked on average cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify:

4. Did you use smokeless tobacco products, nicotine-containing products (e.g., gum or patch), or other smoking cessation products this week?

Yes No

If yes, what type (smokeless tobacco, pharmaceutical nicotine replacement products [gum / patch / other], other nicotine products [e.g., lozenges])?

5. I have consumed on average the following number of snus sachets per day:

Sachet Size:

Large (1g)

Small (0.5g)

6. I have experienced the following Adverse Events:

7. I think the Adverse Event is related to the snus product:

Correct

Incorrect

Don't Know

I have not experienced an Adverse Event

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Page Version No. WEEK_4 (v1, 25-MAR-2009)

Document Number

Initials:

Subject #:

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion:

1. I have not smoked any cigarettes at all during the past week (1 or 2 puffs = 1 cigarette)

Correct Incorrect

2. I have smoked on average cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify:

4. Did you use smokeless tobacco products, nicotine-containing products (e.g., gum or patch), or other smoking cessation products this week?

Yes No

If yes, what type (smokeless tobacco, pharmaceutical nicotine replacement products [gum / patch / other], other nicotine products [e.g., lozenges])?

5. I have consumed on average the following number of snus sachets per day:

Sachet Size:

Large (1g)

Small (0.5g)

6. I have experienced the following Adverse Events:

7. I think the Adverse Event is related to the snus product:

Correct

Incorrect

Don't Know

I have not experienced an Adverse Event

Verified Approved Locked Frozen

Page Version No. WEEK_5 (v1, 25-MAR-2009)

Document Number

Initials:

Subject #:

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion:

1. I have not smoked any cigarettes at all during the past week (1 or 2 puffs = 1 cigarette)

Correct Incorrect

2. I have smoked on average cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify:

4. Did you use smokeless tobacco products, nicotine-containing products (e.g., gum or patch), or other smoking cessation products this week?

Yes No

If yes, what type (smokeless tobacco, pharmaceutical nicotine replacement products [gum / patch / other], other nicotine products [e.g., lozenges])?

5. I have consumed on average the following number of snus sachets per day:

Sachet Size:

Large (1g)

Small (0.5g)

6. I have experienced the following Adverse Events:

7. I think the Adverse Event is related to the snus product:

Correct

Incorrect

Don't Know

I have not experienced an Adverse Event

Verified Approved Locked Frozen

Page Version No. WEEK_6 (v1, 25-MAR-2009)

Document Number

Initials:

Subject #:

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion:

1. I have not smoked any cigarettes at all during the past week (1 or 2 puffs = 1 cigarette)

Correct Incorrect

2. I have smoked on average cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify:

4. Did you use smokeless tobacco products, nicotine-containing products (e.g., gum or patch), or other smoking cessation products this week?

Yes No

If yes, what type (smokeless tobacco, pharmaceutical nicotine replacement products [gum / patch / other], other nicotine products [e.g., lozenges])?

5. I have consumed on average the following number of snus sachets per day:

Sachet Size:

Large (1g)

Small (0.5g)

6. I have experienced the following Adverse Events:

7. I think the Adverse Event is related to the snus product:

Correct

Incorrect

Don't Know

I have not experienced an Adverse Event

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Page Version No. WEEK_7 (v1, 25-MAR-2009)

Document Number

Initials:

Subject #:

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STUDY PRODUCT USE DIARY

During the past week:

Date of completion:

1. I have not smoked any cigarettes at all during the past week (1 or 2 puffs = 1 cigarette)

Correct Incorrect

2. I have smoked on average cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify:

4. Did you use smokeless tobacco products, nicotine-containing products (e.g., gum or patch), or other smoking cessation products this week?

Yes No

If yes, what type (smokeless tobacco, pharmaceutical nicotine replacement products [gum / patch / other], other nicotine products [e.g., lozenges])?

5. I have consumed on average the following number of snus sachets per day:

Sachet Size:

Large (1g)

Small (0.5g)

6. I have experienced the following Adverse Events:

7. I think the Adverse Event is related to the snus product:

Correct

Incorrect

Don't Know

I have not experienced an Adverse Event

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Page Version No. WEEK_8 (v1, 25-MAR-2009)

Document Number

Initials:

Subject #:

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion:

1. I have not smoked any cigarettes at all during the past week (1 or 2 puffs = 1 cigarette)

Correct Incorrect

2. I have smoked on average cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify:

4. Did you use smokeless tobacco products, nicotine-containing products (e.g., gum or patch), or other smoking cessation products this week?

Yes No

If yes, what type (smokeless tobacco, pharmaceutical nicotine replacement products [gum / patch / other], other nicotine products [e.g., lozenges])?

5. I have consumed on average the following number of snus sachets per day:

Sachet Size:

Large (1g)

Small (0.5g)

6. I have experienced the following Adverse Events:

7. I think the Adverse Event is related to the snus product:

Correct

Incorrect

Don't Know

I have not experienced an Adverse Event

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Page Version No. WEEK_9 (v1, 25-MAR-2009)

Document Number

Initials:

Subject #:

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion:

1. I have not smoked any cigarettes at all during the past week (1 or 2 puffs = 1 cigarette)

Correct Incorrect

2. I have smoked on average cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify:

4. Did you use smokeless tobacco products, nicotine-containing products (e.g., gum or patch), or other smoking cessation products this week?

Yes No

If yes, what type (smokeless tobacco, pharmaceutical nicotine replacement products [gum / patch / other], other nicotine products [e.g., lozenges])?

5. I have consumed on average the following number of snus sachets per day:

Sachet Size:

Large (1g)

Small (0.5g)

6. I have experienced the following Adverse Events:

7. I think the Adverse Event is related to the snus product:

Correct

Incorrect

Don't Know

I have not experienced an Adverse Event

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Page Version No. WEEK_10 (v1, 25-MAR-2009)

Document Number

Initials:

Subject #:

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion:

1. I have not smoked any cigarettes at all during the past week (1 or 2 puffs = 1 cigarette)

Correct Incorrect

2. I have smoked on average cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify:

4. Did you use smokeless tobacco products, nicotine-containing products (e.g., gum or patch), or other smoking cessation products this week?

Yes No

If yes, what type (smokeless tobacco, pharmaceutical nicotine replacement products [gum / patch / other], other nicotine products [e.g., lozenges])?

5. I have consumed on average the following number of snus sachets per day:

Sachet Size:

Large (1g)

Small (0.5g)

6. I have experienced the following Adverse Events:

7. I think the Adverse Event is related to the snus product:

Correct

Incorrect

Don't Know

I have not experienced an Adverse Event

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Page Version No. WEEK_11 (v1, 25-MAR-2009)

Document Number

Initials:

Subject #:

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion:

1. I have not smoked any cigarettes at all during the past week (1 or 2 puffs = 1 cigarette)

Correct Incorrect

2. I have smoked on average cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify:

4. Did you use smokeless tobacco products, nicotine-containing products (e.g., gum or patch), or other smoking cessation products this week?

Yes No

If yes, what type (smokeless tobacco, pharmaceutical nicotine replacement products [gum / patch / other], other nicotine products [e.g., lozenges])?

5. I have consumed on average the following number of snus sachets per day:

Sachet Size:

Large (1g)

Small (0.5g)

6. I have experienced the following Adverse Events:

7. I think the Adverse Event is related to the snus product:

Correct

Incorrect

Don't Know

I have not experienced an Adverse Event

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Page Version No. WEEK_12 (v1, 25-MAR-2009)

Document Number

Initials:

Subject #:

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion:

1. I have not smoked any cigarettes at all during the past week (1 or 2 puffs = 1 cigarette)

Correct Incorrect

2. I have smoked on average cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify:

4. Did you use smokeless tobacco products, nicotine-containing products (e.g., gum or patch), or other smoking cessation products this week?

Yes No

If yes, what type (smokeless tobacco, pharmaceutical nicotine replacement products [gum / patch / other], other nicotine products [e.g., lozenges])?

5. I have consumed on average the following number of snus sachets per day:

Sachet Size:

Large (1g)

Small (0.5g)

6. I have experienced the following Adverse Events:

7. I think the Adverse Event is related to the snus product:

Correct

Incorrect

Don't Know

I have not experienced an Adverse Event

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Page Version No. WEEK_13 (v1, 25-MAR-2009)

Document Number

Initials:

Subject #:

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion:

1. I have not smoked any cigarettes at all during the past week (1 or 2 puffs = 1 cigarette)

Correct Incorrect

2. I have smoked on average cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify:

4. Did you use smokeless tobacco products, nicotine-containing products (e.g., gum or patch), or other smoking cessation products this week?

Yes No

If yes, what type (smokeless tobacco, pharmaceutical nicotine replacement products [gum / patch / other], other nicotine products [e.g., lozenges])?

5. I have consumed on average the following number of snus sachets per day:

Sachet Size:

Large (1g)

Small (0.5g)

6. I have experienced the following Adverse Events:

7. I think the Adverse Event is related to the snus product:

Correct

Incorrect

Don't Know

I have not experienced an Adverse Event

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Page Version No. WEEK_14 (v1, 25-MAR-2009)

Document Number

Initials:

Subject #:

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion:

1. I have not smoked any cigarettes at all during the past week (1 or 2 puffs = 1 cigarette)

Correct Incorrect

2. I have smoked on average cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify:

4. Did you use smokeless tobacco products, nicotine-containing products (e.g., gum or patch), or other smoking cessation products this week?

Yes No

If yes, what type (smokeless tobacco, pharmaceutical nicotine replacement products [gum / patch / other], other nicotine products [e.g., lozenges])?

5. I have consumed on average the following number of snus sachets per day:

Sachet Size:

Large (1g)

Small (0.5g)

6. I have experienced the following Adverse Events:

7. I think the Adverse Event is related to the snus product:

Correct

Incorrect

Don't Know

I have not experienced an Adverse Event

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Page Version No. WEEK_15 (v1, 25-MAR-2009)

Document Number

Initials:

Subject #:

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion:

1. I have not smoked any cigarettes at all during the past week (1 or 2 puffs = 1 cigarette)

Correct Incorrect

2. I have smoked on average cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify:

4. Did you use smokeless tobacco products, nicotine-containing products (e.g., gum or patch), or other smoking cessation products this week?

Yes No

If yes, what type (smokeless tobacco, pharmaceutical nicotine replacement products [gum / patch / other], other nicotine products [e.g., lozenges])?

5. I have consumed on average the following number of snus sachets per day:

Sachet Size:

Large (1g)

Small (0.5g)

6. I have experienced the following Adverse Events:

7. I think the Adverse Event is related to the snus product:

Correct

Incorrect

Don't Know

I have not experienced an Adverse Event

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Page Version No. WEEK_16 (v1, 25-MAR-2009)

Document Number

Initials:

Subject #:

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion:

1. I have not smoked any cigarettes at all during the past week (1 or 2 puffs = 1 cigarette)

Correct Incorrect

2. I have smoked on average cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify:

4. Did you use smokeless tobacco products, nicotine-containing products (e.g., gum or patch), or other smoking cessation products this week?

Yes No

If yes, what type (smokeless tobacco, pharmaceutical nicotine replacement products [gum / patch / other], other nicotine products [e.g., lozenges])?

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Page Version No. WEEK_17 (v1, 25-MAR-2009)

Document Number

Initials:

Subject #:

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion:

1. I have not smoked any cigarettes at all during the past week (1 or 2 puffs = 1 cigarette)

Correct Incorrect

2. I have smoked on average cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify:

4. Did you use smokeless tobacco products, nicotine-containing products (e.g., gum or patch), or other smoking cessation products this week?

Yes No

If yes, what type (smokeless tobacco, pharmaceutical nicotine replacement products [gum / patch / other], other nicotine products [e.g., lozenges])?

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Page Version No. WEEK_18 (v1, 25-MAR-2009)

Document Number

Initials:

Subject #:

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion:

1. I have not smoked any cigarettes at all during the past week (1 or 2 puffs = 1 cigarette)

Correct Incorrect

2. I have smoked on average cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify:

4. Did you use smokeless tobacco products, nicotine-containing products (e.g., gum or patch), or other smoking cessation products this week?

Yes No

If yes, what type (smokeless tobacco, pharmaceutical nicotine replacement products [gum / patch / other], other nicotine products [e.g., lozenges])?

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Page Version No. WEEK_19 (v1, 25-MAR-2009)

Document Number

Initials:

Subject #:

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion:

1. I have not smoked any cigarettes at all during the past week (1 or 2 puffs = 1 cigarette)

Correct Incorrect

2. I have smoked on average cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify:

4. Did you use smokeless tobacco products, nicotine-containing products (e.g., gum or patch), or other smoking cessation products this week?

Yes No

If yes, what type (smokeless tobacco, pharmaceutical nicotine replacement products [gum / patch / other], other nicotine products [e.g., lozenges])?

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Page Version No. WEEK_20 (v1, 25-MAR-2009)

Document Number

Initials:

Subject #:

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion:

1. I have not smoked any cigarettes at all during the past week (1 or 2 puffs = 1 cigarette)

Correct Incorrect

2. I have smoked on average cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify:

4. Did you use smokeless tobacco products, nicotine-containing products (e.g., gum or patch), or other smoking cessation products this week?

Yes No

If yes, what type (smokeless tobacco, pharmaceutical nicotine replacement products [gum / patch / other], other nicotine products [e.g., lozenges])?

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Page Version No. WEEK_21 (v1, 25-MAR-2009)

Document Number

Initials:

Subject #:

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion:

1. I have not smoked any cigarettes at all during the past week (1 or 2 puffs = 1 cigarette)

Correct Incorrect

2. I have smoked on average cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify:

4. Did you use smokeless tobacco products, nicotine-containing products (e.g., gum or patch), or other smoking cessation products this week?

Yes No

If yes, what type (smokeless tobacco, pharmaceutical nicotine replacement products [gum / patch / other], other nicotine products [e.g., lozenges])?

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Page Version No. WEEK_22 (v1, 25-MAR-2009)

Document Number

Initials:

Subject #:

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion:

1. I have not smoked any cigarettes at all during the past week (1 or 2 puffs = 1 cigarette)

Correct Incorrect

2. I have smoked on average cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify:

4. Did you use smokeless tobacco products, nicotine-containing products (e.g., gum or patch), or other smoking cessation products this week?

Yes No

If yes, what type (smokeless tobacco, pharmaceutical nicotine replacement products [gum / patch / other], other nicotine products [e.g., lozenges])?

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Page Version No. WEEK_23 (v1, 25-MAR-2009)

Document Number

Initials:

Subject #:

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion:

1. I have not smoked any cigarettes at all during the past week (1 or 2 puffs = 1 cigarette)

Correct Incorrect

2. I have smoked on average cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify:

4. Did you use smokeless tobacco products, nicotine-containing products (e.g., gum or patch), or other smoking cessation products this week?

Yes No

If yes, what type (smokeless tobacco, pharmaceutical nicotine replacement products [gum / patch / other], other nicotine products [e.g., lozenges])?

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Page Version No. WEEK_24 (v1, 25-MAR-2009)

Document Number

Initials:

Subject #:

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion:

1. I have not smoked any cigarettes at all during the past week (1 or 2 puffs = 1 cigarette)

Correct Incorrect

2. I have smoked on average cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify:

4. Did you use smokeless tobacco products, nicotine-containing products (e.g., gum or patch), or other smoking cessation products this week?

Yes No

If yes, what type (smokeless tobacco, pharmaceutical nicotine replacement products [gum / patch / other], other nicotine products [e.g., lozenges])?

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Page Version No. WEEK_25 (v1, 25-MAR-2009)

Document Number

Initials:

Subject #:

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion:

1. I have not smoked any cigarettes at all during the past week (1 or 2 puffs = 1 cigarette)

Correct Incorrect

2. I have smoked on average cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify:

4. Did you use smokeless tobacco products, nicotine-containing products (e.g., gum or patch), or other smoking cessation products this week?

Yes No

If yes, what type (smokeless tobacco, pharmaceutical nicotine replacement products [gum / patch / other], other nicotine products [e.g., lozenges])?

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Page Version No. WEEK_26 (v1, 25-MAR-2009)

Document Number

Initials:

Subject #:

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion:

1. I have not smoked any cigarettes at all during the past week (1 or 2 puffs = 1 cigarette)

Correct Incorrect

2. I have smoked on average cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify:

4. Did you use smokeless tobacco products, nicotine-containing products (e.g., gum or patch), or other smoking cessation products this week?

Yes No

If yes, what type (smokeless tobacco, pharmaceutical nicotine replacement products [gum / patch / other], other nicotine products [e.g., lozenges])?

Verified Approved Locked Frozen

Page Version No. WEEK_27 (v1, 25-MAR-2009)

Document Number

Initials:

Subject #:

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion:

1. I have not smoked any cigarettes at all during the past week (1 or 2 puffs = 1 cigarette)

Correct Incorrect

2. I have smoked on average cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify:

4. Did you use smokeless tobacco products, nicotine-containing products (e.g., gum or patch), or other smoking cessation products this week?

Yes No

If yes, what type (smokeless tobacco, pharmaceutical nicotine replacement products [gum / patch / other], other nicotine products [e.g., lozenges])?

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Page Version No. WEEK_28 (v1, 25-MAR-2009)

Document Number