CRF Report for Study E7694105D

Report run by Brian Saari at 22-FEB-2013 12:01:10

Report Parameters

Site:	**L0689282_2**
Discrepancy status choice:	**All statuses**
Approval status choice:	**All statuses**
Verification status choice:	**All statuses**
Starting patient:	**R2004**
Ending patient:	**R2004**

Legend: How different values appear in the report

Prompt	Abc 123
Data value	Abc 123
Data value with discrepancy	**Abc 123**

All time stamps displayed in this report are in the timezone of the database server.

The data contained in this report is current at the time of printing (time as shown above)

Study # 7694-105 / Protocol # SM 08-01

Initials: (b)

Subject #: R2004

WEEK 1 Is Blank ☐

STUDY PRODUCT USE DIARY

During the past week: Date of completion: 30-MAR-2009

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 15 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) 6
Small (0.5g) 3

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_1 (v1, 25-MAR-2009)

Document Number R247721513

Study # 7694-105 / Protocol # SM 08-01

Initials: (b)

Subject #: R2004

WEEK 2 Is Blank ☐

STUDY PRODUCT USE DIARY

During the past week: Date of completion: 04-APR-2009

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 11 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) 10
Small (0.5g) 6

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

Study # 7694-105 / Protocol # SM 08-01

Initials: (b)

Subject #: R2004

WEEK 3 Is Blank ☐

STUDY PRODUCT USE DIARY

During the past week: Date of completion: 12-APR-2009

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 6 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) 13
Small (0.5g) 6

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

Study # 7694-105 / Protocol # SM 08-01

Initials: (b)

Subject #: R2004

WEEK 4 Is Blank ☐

STUDY PRODUCT USE DIARY

During the past week: Date of completion: 19-APR-2009

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 6 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) 13
Small (0.5g) 6

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 ☑

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Study # 7694-105 / Protocol # SM 08-01

Initials: (b)

Subject #: R2004

WEEK 5 Is Blank ☐

STUDY PRODUCT USE DIARY

During the past week: Date of completion: 26-APR-2009

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 4 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) 13
Small (0.5g) 12

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

Links to Discrepancy and Audit Sections

Click here to navigate to audit history for this CRF

Study # 7694-105 / Protocol # SM 08-01

Initials: (b)

Subject #: R2004

WEEK 6 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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Subject #: R2004

WEEK 7 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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Subject #: R2004

WEEK 8 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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Initials: (b)

Subject #: R2004

WEEK 9 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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WEEK 10 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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Initials: (b)

Subject #: R2004

WEEK 11 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

Study # 7694-105 / Protocol # SM 08-01

Initials: (b)

Subject #: R2004

WEEK 12 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

Study # 7694-105 / Protocol # SM 08-01

Initials: (b)

Subject #: R2004

WEEK 13 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

Study # 7694-105 / Protocol # SM 08-01

Initials: (b)

Subject #: R2004

WEEK 14 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

Study # 7694-105 / Protocol # SM 08-01

Initials: (b)

Subject #: R2004

WEEK 15 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

Study # 7694-105 / Protocol # SM 08-01

Initials: (b)

Subject #: R2004

WEEK 16 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

Study # 7694-105 / Protocol # SM 08-01

Initials: (b)

Subject #: R2004

FOLLOW-UP WK 17 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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Initials: (b)

Subject #: R2004

FOLLOW-UP WK 18 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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Initials: (b)

Subject #: R2004

FOLLOW-UP WK 19 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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Initials: (b)

Subject #: R2004

FOLLOW-UP WK 20 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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Initials: (b)

Subject #: R2004

FOLLOW-UP WK 21 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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Initials: (b)

Subject #: R2004

FOLLOW-UP WK 22 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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Initials: (b)

Subject #: R2004

FOLLOW-UP WK 23 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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Initials: (b)

Subject #: R2004

FOLLOW-UP WK 24 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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Initials: (b)

Subject #: R2004

FOLLOW-UP WK 25 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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Initials: (b)

Subject #: R2004

FOLLOW-UP WK 26 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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Initials: (b)

Subject #: R2004

FOLLOW-UP WK 27 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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Initials: (b)

Subject #: R2004

FOLLOW-UP WK 28 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])?

Appendix: Audit and Discrepancy Information

Audit History Report

This section lists audited data that meets the parameters set when the report was run. It may not include all of the audited data in a particular CRF. Refer to the documentation for a complete description of the parameters that can affect this report.

Document #: **R247723013**

Patient Site	Visit Visit Date	CRF CRF Page	
R2004 L0689282_2	Week 5	Week_5 05	
Section Section Date	**Qualifying Prompt**	**Qualifying Value**	**Section Visit**
Study Diary	Page number	5	Week 5

Group #	Group Name
1	DRUGSCR

Field Row	Changed From Changed To	Impact on resequence	On By	Reason Comment
1. I have not smoked any cigarettes at a (1) 1	INCORRECT		20-MAY-2009 14:31:31 Amanda Lynn	Data Entry Error

Discrepancy Detail Report

Deleted CRFs Report