

CRF Report for Study E7694105D

Report run by Brian Saari at 25-FEB-2013 12:39:23

Report Parameters

Site: P3880_0342

Discrepancy status choice: All statuses

Approval status choice: All statuses

Verification status choice: All statuses

Starting patient: R4109

Ending patient: R4109

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)

Initials:

(b)

Subject #:

R4109

WEEK 1

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 30-JUL-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 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:

STAPH INFECTION DOXYCYCLINE

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 R291372513

Initials:

(b)

Subject #:

R4109

WEEK 2

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 06-AUG-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 12 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) 0

Small (0.5g) 10

6. I have experienced the following Adverse Events:

NONE

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_2 (v1, 25-MAR-2009)

Document Number R291373613

Initials:

(b)

Subject #:

R4109

WEEK 3

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 13-AUG-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 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_3 (v1, 25-MAR-2009)

Document Number

Initials:

(b)

Subject #:

R4109

WEEK 4

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 20-AUG-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 10 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) 0

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

Verified Approved Locked Frozen

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

Document Number R291381713

Initials:

(b)

Subject #:

R4109

WEEK 5

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 27-AUG-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 16 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) 5

Small (0.5g) 0

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 R291381913

Initials:

(b) _____

Subject #:

R4109

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

Verified Approved Locked Frozen

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

Document Number R291382513

Initials:

(b) _____

Subject #:

R4109

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

Verified Approved Locked Frozen

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

Document Number R291382913

Initials:

(b) _____

Subject #:

R4109

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

Verified Approved Locked Frozen

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

Document Number R291383013

Initials:

(b) _____

Subject #:

R4109

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

Verified Approved Locked Frozen

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

Document Number R291383113

Initials:

(b)

Subject #:

R4109

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

Verified Approved Locked Frozen

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

Document Number

Initials:

(b) _____

Subject #:

R4109

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

Verified Approved Locked Frozen

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

Document Number R291383413

Initials:

(b) _____

Subject #:

R4109

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

Verified Approved Locked Frozen

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

Document Number R291383613

Initials:

(b) _____

Subject #:

R4109

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

Verified Approved Locked Frozen

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

Document Number R291383713

Initials:

(b)

Subject #:

R4109

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

Verified Approved Locked Frozen

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

Document Number

Initials:

(b)

Subject #:

R4109

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

Verified Approved Locked Frozen

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

Document Number R291383913

Initials:

(b) _____

Subject #:

R4109

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

Verified Approved Locked Frozen

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

Document Number R291384013

Initials:

(b) _____

Subject #:

R4109

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])?

Verified Approved Locked Frozen

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

Document Number R291384213

Initials:

(b) _____

Subject #:

R4109

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])?

Verified Approved Locked Frozen

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

Document Number R291384313

Initials:

(b) _____

Subject #:

R4109

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])?

Verified Approved Locked Frozen

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

Document Number R291384413

Initials:

(b) _____

Subject #:

R4109

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])?

Verified Approved Locked Frozen

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

Document Number R291384513

Initials:

(b) _____

Subject #:

R4109

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])?

Verified Approved Locked Frozen

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

Document Number R291384613

Initials:

(b) _____

Subject #:

R4109

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])?

Verified Approved Locked Frozen

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

Document Number R291384813

Initials:

(b) _____

Subject #:

R4109

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])?

Verified Approved Locked Frozen

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

Document Number R291384913

Initials:

(b) _____

Subject #:

R4109

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])?

Verified Approved Locked Frozen

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

Document Number R291385013

Initials:

(b) _____

Subject #:

R4109

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])?

Verified Approved Locked Frozen

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

Document Number R291385213

Initials:

(b) _____

Subject #:

R4109

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])?

Verified Approved Locked Frozen

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

Document Number R291385313

Initials:

(b) _____

Subject #:

R4109

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])?

Verified Approved Locked Frozen

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

Document Number R291385413

Initials:

(b) _____

Subject #:

R4109

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])?

Verified Approved Locked Frozen

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

Document Number R291385513

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.

Discrepancy Detail Report

Deleted CRFs Report