

# CRF Report for Study E7694105D

Report run by Brian Saari at 21-FEB-2013 12:37:23

## Report Parameters

Site: CDB\_001

Discrepancy status choice: All statuses

Approval status choice: All statuses

Verification status choice: All statuses

Starting patient: R1035

Ending patient: R1035

### Legend: How different values appear in the report

Prompt	Abc 123
Data value	Abc 123
Data value with discrepancy	<b>Abc 123</b>

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 #:

R1035

WEEK 1

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 05-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:

BURNING SNESATION WHEN FIRST PUTTING IN SNUS-BRIEFLY

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 R273422213

## **Links to Discrepancy and Audit Sections**

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[Click here to navigate to discrepancy details for this CRF](#)

Initials:

(b)

Subject #:

R1035

WEEK 2

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 12-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 19 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) 0

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 R273675713

Initials:

(b)

Subject #:

R1035

WEEK 3

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 19-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 17 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) 7

Small (0.5g) 0

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\_3 (v1, 25-MAR-2009)

Document Number R273676313

Initials:

(b)

Subject #:

R1035

WEEK 4

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 26-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:

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\_4 (v1, 25-MAR-2009)

Document Number R273676513

Initials:

(b)

Subject #:

R1035

WEEK 5

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 02-SEP-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:

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\_5 (v1, 25-MAR-2009)

Document Number R273676813

Initials:

(b)

Subject #:

R1035

WEEK 6

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 09-SEP-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:

SORE LEFT ELBOW PRESCRIPTION ANTI-INFLAMMATORY

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

## **Links to Discrepancy and Audit Sections**

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Initials:

(b)

Subject #:

R1035

WEEK 7

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 16-SEP-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) 6

Small (0.5g) 0

6. I have experienced the following Adverse Events:

STOPPED TAKING MELOXICAM 9/13/09 FOR ELBOW

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 R273679613

Initials:

(b)

Subject #:

R1035

WEEK 8

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 23-SEP-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:

9-20 USING ABSORBINE TOPICAL ANALGESIC LT ELBOW. CHEST CONGESTION 9-20 & COUG<sub>1</sub>

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 R273682113

## OverFlow Section For Document Number R273682113

- 1 9-20 USING ABSORBINE TOPICAL ANALGESIC LT ELBOW. CHEST CONGESTION 9-20 & COUGHING-STOPPED SNUS/AIRBORNE & EQUATE. 9-24 START SNUS ALSO STOPPED AIRBORNE & EQUATE.

## **Links to Discrepancy and Audit Sections**

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Initials:

(b)

Subject #:

R1035

WEEK 9

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 30-SEP-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:

9-24START SNUS URI STOPPED 9-24

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 R273684013

## **Links to Discrepancy and Audit Sections**

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Initials:

(b)

Subject #:

R1035

WEEK 10

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 08-OCT-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:

10-1-09 STARTED MELOXICAM 15 MG. ONE A DAY, CYCLOBENAPRINE 10 MG. 3 TIMES DAI<sub>1</sub>

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 R273684413

## OverFlow Section For Document Number R273684413

- 1 10-1-09 STARTED MELOXICAM 15 MG. ONE A DAY, CYCLOBENAPRINE 10 MG. 3 TIMES DAILY 10-2-09, STOPPED ABOVE MEDICATION STILL HAVE SOME ELBOW PAIN

## **Links to Discrepancy and Audit Sections**

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Initials:

(b)

Subject #:

R1035

WEEK 11

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 15-OCT-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:

LEFT ELBOW PAIN

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 R281941513

Initials:

(b)

Subject #:

R1035

WEEK 12

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 22-OCT-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:

10-15-09 STARTED METHYL PREDNISOLONE 4 MG. FOR LEFT ELBOW 6-5-4-3-2-1/DAY, ST<sub>1</sub>

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 R281943213

## OverFlow Section For Document Number R281943213

- 1 10-15-09 STARTED METHYL PREDNISOLONE 4 MG. FOR LEFT ELBOW 6-5-4-3-2-1/DAY, STOPPED 10-21-09, 10-19-09 NO PAIN IN ELBOW

## **Links to Discrepancy and Audit Sections**

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Initials:

(b)

Subject #:

R1035

WEEK 13

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 29-OCT-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 13 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) 7

Small (0.5g) 0

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\_13 (v1, 25-MAR-2009)

Document Number R281943613

Initials:

(b)

Subject #:

R1035

WEEK 14

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 05-NOV-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:

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\_14 (v1, 25-MAR-2009)

Document Number R281944113

Initials:

(b)

Subject #:

R1035

WEEK 15

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 12-NOV-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 13 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) 7

Small (0.5g) 0

6. I have experienced the following Adverse Events:

11-9-09 SORE THROAT/CHEST CONGESTION, START EQUATE ALLERGY RELIEF 10 MG 1 A D<sub>1</sub>

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 R281944213

## OverFlow Section For Document Number R281944213

- 1 11-9-09 SORE THROAT/CHEST CONGESTION, START EQUATE ALLERGY RELIEF 10 MG 1 A DAY.  
11-11-09 STOPPED TAKING ABOVE-THROAT & CHEST OK.

## **Links to Discrepancy and Audit Sections**

[Click here to navigate to audit history for this CRF](#)

[Click here to navigate to discrepancy details for this CRF](#)

Initials:

(b)

Subject #:

R1035

WEEK 16

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 20-NOV-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:

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\_16 (v1, 25-MAR-2009)

Document Number R281945013

Initials:

(b)

Subject #:

R1035

FOLLOW-UP WK 17

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 25-NOV-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 14 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 R293274113

Initials:

(b)

Subject #:

R1035

FOLLOW-UP WK 18

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 02-DEC-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])?

Verified  Approved  Locked  Frozen

Page Version No. WEEK\_18 (v1, 25-MAR-2009)

Document Number R293274313

Initials:

(b)

Subject #:

R1035

FOLLOW-UP WK 19

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 09-DEC-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])?

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Page Version No. WEEK\_19 (v1, 25-MAR-2009)

Document Number R293274613

Initials:

(b)

Subject #:

R1035

FOLLOW-UP WK 20

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 16-DEC-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])?

Verified  Approved  Locked  Frozen

Page Version No. WEEK\_20 (v1, 25-MAR-2009)

Document Number R293274713

Initials:

(b)

Subject #:

R1035

FOLLOW-UP WK 21

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 23-DEC-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 17 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])?

2 SNUS DAILY (CONFIRMED TO BE CAMEL SNUS-NON MENTHOL)

Verified  Approved  Locked  Frozen

Page Version No. WEEK\_21 (v1, 25-MAR-2009)

Document Number R293275113

Initials:

(b)

Subject #:

R1035

FOLLOW-UP WK 22

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 30-DEC-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])?

2 SNUS DAILY (CONFIRMED TO BE CAMEL SNUS-NON MENTHOL)

Verified  Approved  Locked  Frozen

Page Version No. WEEK\_22 (v1, 25-MAR-2009)

Document Number R293275513

Initials:

(b)

Subject #:

R1035

FOLLOW-UP WK 23

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 06-JAN-2010

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 17 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])?

2 SNUS DAILY (CONFIRMED TO BE CAMEL SNUS-NON MENTHOL)

Verified  Approved  Locked  Frozen

Page Version No. WEEK\_23 (v1, 25-MAR-2009)

Document Number R293275813

## **Links to Discrepancy and Audit Sections**

[Click here to navigate to audit history for this CRF](#)

Initials:

(b)

Subject #:

R1035

FOLLOW-UP WK 24

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 13-JAN-2010

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 17 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])?

2 SNUS DAILY (CONFIRMED TO BE CAMEL SNUS-NON MENTHOL)

Verified  Approved  Locked  Frozen

Page Version No. WEEK\_24 (v1, 25-MAR-2009)

Document Number R293276613

Initials:

(b)

Subject #:

R1035

FOLLOW-UP WK 25

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 20-JAN-2010

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 17 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])?

2 SNUS DAILY (CONFIRMED TO BE CAMEL SNUS-NON MENTHOL)

Verified  Approved  Locked  Frozen

Page Version No. WEEK\_25 (v1, 25-MAR-2009)

Document Number R293277013

Initials:

(b)

Subject #:

R1035

FOLLOW-UP WK 26

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 27-JAN-2010

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])?

1 SNUS DAILY (CONFIRMED TO BE CAMEL SNUS-NON MENTHOL)

Verified  Approved  Locked  Frozen

Page Version No. WEEK\_26 (v1, 25-MAR-2009)

Document Number R293277213

Initials:

(b)

Subject #:

R1035

FOLLOW-UP WK 27

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 03-FEB-2010

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])?

1 SNUS DAILY (CONFIRMED TO BE CAMEL SNUS-NON MENTHOL)

Verified  Approved  Locked  Frozen

Page Version No. WEEK\_27 (v1, 25-MAR-2009)

Document Number R293277313

Initials:

(b)

Subject #:

R1035

FOLLOW-UP WK 28

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 10-FEB-2010

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 17 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])?

1 SNUS DAILY (CONFIRMED TO BE CAMEL SNUS-NON MENTHOL)

Verified  Approved  Locked  Frozen

Page Version No. WEEK\_28 (v1, 25-MAR-2009)

Document Number R293277613

## 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 #:** R273422213

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R1035 CDB_001	Week 1	Week_1 01

<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
Study Diary	Page number	1	Week 1

<b>Group #</b>	<b>Group Name</b>
1	DRUGSCR

<b>Field Row</b>	<b>Changed From Changed To</b>	<b>Impact on On resequence By</b>	<b>Reason Comment</b>
2. I have smoked on average_cigarettes p (1) 1	17.5 18	31-DEC-2009 14:03:29 Sharon Daly	Data Entry Error
5. Large (1g) (2) 1	5.7 6	31-DEC-2009 14:03:29 Sharon Daly	Data Entry Error
Date 1	05-AUG02009	09-OCT-2009 14:41:42 Sharon Daly	Data Entry Error
Date 1	05-AUG02009 05-AUG-2009	09-OCT-2009 14:43:28 Sharon Daly	Data Entry Error

**Document #:** R273676913

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R1035 CDB_001	Week 6	Week_6 06

<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
Study Diary	Page number	6	Week 6

<b>Group #</b>	<b>Group Name</b>
1	DRUGSCR

<b>Field Row</b>	<b>Changed From Changed To</b>	<b>Impact on resequence</b>	<b>On By</b>	<b>Reason Comment</b>
5. Small (0.5g) (3) 1	0 UNKNOWN		14-OCT-2009 11:13:38 Sharon Daly	Pass1
5. Small (0.5g) (3) 1	UNKNOWN UNK		31-MAR-2010 16:42:07 Kryisia Magnuson	ODM/SEC UNKNOWN to UNK

Document #: R273682113

Patient Site	Visit Visit Date	CRF CRF Page
R1035 CDB_001	Week 8	Week_8 08

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Study Diary	Page number	8	Week 8

Group #	Group Name
1	DRUGSCR

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
6. I have experienced the following AEs (3) 1	9-20 USING ABSORBINE TOPICAL ANALGESIC LEFT ELBOW CHEST CONGESTION 9-20 ND COUGHING-STOPPED SNUS/AIRBORNE AND EQUATE 9-24 START SNUS ALSO STOPPED AIRBORNE AND EQUATE CHEST CONGESTION 9-20 & COUGHING	31-DEC-2009 14:26:04 Sharon Daly	Data Entry Error
6. I have experienced the following AEs (3) 1	CHEST CONGESTION 9-20 & COUGHING 9-20 USING ABSORBINE TOPICAL ANALGESIC LT ELBOW. CHEST CONGESTION 9-20 & COUGHING-STOPPED SNUS/AIRBORNE & EQUATE. 9-24 START SNUS ALSO STOPPED AIRBORNE & EQUATE.	10-FEB-2010 18:26:49 Christina Breedlove	Data Entry Error per query

**Document #:** R273684413

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R1035 CDB_001	Week 10	Week_10 10

<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
Study Diary	Page number	10	Week 10

<b>Group #</b>	<b>Group Name</b>
1	DRUGSCR

<b>Field Row</b>	<b>Changed From Changed To</b>	<b>Impact on On resequence By</b>	<b>Reason Comment</b>
6. (3) 1	I have experienced the following AEs 10-1STARTED MELOXICAM 15 MG. ONE A DAY CYCLOBENAPRINE 10 MG. 3 TIMES DAILY 10-2 STOPPED ABOVE MEDICATION STILL HAVE SOME ELBOW PAIN 10-1-09 STARTED MELOXICAM 15 MG. ONE A DAY, CYCLOBENAPRINE 10 MG. 3 TIMES DAILY 10-2-09, STOPPED ABOVE MEDICATION STILL HAVE SOME ELBOW PAIN	31-DEC-2009 14:34:40 Sharon Daly	Data Entry Error

**Document #:** R281943213

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R1035 CDB_001	Week 12	Week_12 12

<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
Study Diary	Page number	12	Week 12

<b>Group #</b>	<b>Group Name</b>
1	DRUGSCR

<b>Field Row</b>	<b>Changed From Changed To</b>	<b>Impact on On resequence By</b>	<b>Reason Comment</b>
6. I have experienced the following AEs (3) 1	NO PAIN IN ELBOW ON 10-19-09 10-15-09 STARTED METHYL PREDNISOLONE 4 MG. FOR LEFT ELBOW 6-5-4-3-2-1/DAY, STOPPED 10-21-09, 10-19-09 NO PAIN IN ELBOW	31-DEC-2009 14:37:14 Sharon Daly	Data Entry Error
Date 1	22-OCT-2009	25-NOV-2009 15:54:02 Christina Breedlove	Data Entry Error

**Document #:** R281944213

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R1035 CDB_001	Week 15	Week_15 15

<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
Study Diary	Page number	15	Week 15

<b>Group #</b>	<b>Group Name</b>
1	DRUGSCR

<b>Field Row</b>	<b>Changed From Changed To</b>	<b>Impact on On resequence By</b>	<b>Reason Comment</b>
6. I have experienced the following AEs (3) 1	SORE THROAT/CHEST CONGESTION FROM 11-19-09 TO 11-11-09 11-9-09 SORE THROAT/CHEST CONGESTION, START EQUATE ALLERGY RELIEF 10 MG 1 A DAY. 11-11-09 STOPPED TAKING ABOVE-THROAT & CHEST OK.	10-FEB-2010 18:31:10 Christina Breedlove	Data Entry Error per query

**Document #:** R293275813

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R1035 CDB_001	Follow-Up Wk 23	Week_23 23

<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
Study Diary	Page number	23	Follow-Up Wk 23

<b>Group #</b>	<b>Group Name</b>
1	DRUGSCR

<b>Field Row</b>	<b>Changed From Changed To</b>	<b>Impact on On resequence By</b>	<b>Reason Comment</b>
4. Yes specify: (2) 1	2 SNUS DAILY (CONFIRMED TO BE CAMEL SNUS-NON MENTHOL) 2 SNUS DAILY (CONFIRMED TO BE CAMEL SNUS-NON MENTHOL)	03-JUN-2010 15:02:01 Krysia Magnuson	ODM/SEC CONFIRMED TO CONFIRMED

# Discrepancy Detail Report

Document #: R273422213

Discrepancy ID: 21182511                      Site: CDB\_001                      Patient: R1035  
Visit: WEEK 1                      Visit Date:  
CRF: WEEK\_1                      Section: STUDY DIARY                      Qualifying Value: 1  
Field: 2. I have smoked on average\_cigarettes p                      Row: 1  
Value Text: 18  
Type: MANUAL                      Status: CURRENT  
Review Status: Resolved-Response Edited  
Discrepancy: Please verify cigarettes should be entered in whole numbers only. Please round up to 18  
Internal Comment: will do  
Resolution Type: Data value changed. Disc no longer applicable.  
Resolution Text:

Discrepancy ID: 21182611                      Site: CDB\_001                      Patient: R1035  
Visit: WEEK 1                      Visit Date:  
CRF: WEEK\_1                      Section: STUDY DIARY                      Qualifying Value: 1  
Field: 5. Large (1g)                      Row: 1  
Value Text: 6  
Type: MANUAL                      Status: CURRENT  
Review Status: Resolved-Response Edited  
Discrepancy: Snus should be entered in whole numbers only, please round up.  
Internal Comment:  
Resolution Type: Data value changed. Disc no longer applicable.  
Resolution Text:

**Document #: R273682113**

**Discrepancy ID:** 21182711

**Site:** CDB\_001

**Patient:** R1035

**Visit:** WEEK 8

**Visit Date:**

**CRF:** WEEK\_8

**Section:** STUDY DIARY

**Qualifying Value:** 8

**Field:** 6. I have experienced the following AEs

**Row:** 1

**Value Text:** 9-20 USING ABSORBINE TOPICAL ANALGESIC LT ELBOW. CHEST CONGESTION 9-20 & COUGHING-STOPPED  
SNUS/AIRBORNE & EQUATE. 9-24 START SNUS ALSO STOPPED AIRBORNE & EQUATE.

**Type:** MANUAL

**Status:** CURRENT

**Review Status:** Resolved-Response Edited

**Discrepancy:** Please enter verbatim.

**Internal Comment:**

**Resolution Type:** Due Diligence

**Resolution Text:**

**Document #: R273684013**

**Discrepancy ID:** 21183411

**Site:** CDB\_001

**Patient:** R1035

**Visit:** WEEK 9

**Visit Date:**

**CRF:** WEEK\_9

**Section:** STUDY DIARY

**Qualifying Value:** 9

**Field:** 6. I have experienced the following AEs

**Row:** 1

**Value Text:** 9-24START SNUS URI STOPPED 9-24

**Type:** MANUAL

**Status:** CURRENT

**Review Status:** Resolved-Response Edited

**Discrepancy:** Please clarify or add punctuation. Also include year when entering date for clarity.

**Internal Comment:** this is taken verbatim as requested/ guidance diary entries

**Resolution Type:** No Action Required

**Resolution Text:**

**Document #: R273684413**

**Discrepancy ID:** 21183611

**Site:** CDB\_001

**Patient:** R1035

**Visit:** WEEK 10

**Visit Date:**

**CRF:** WEEK\_10

**Section:** STUDY DIARY

**Qualifying Value:** 10

**Field:** 6. I have experienced the following AEs

**Row:** 1

**Value Text:** 10-1-09 STARTED MELOXICAM 15 MG. ONE A DAY, CYCLOBENAPRINE 10 MG. 3 TIMES DAILY 10-2-09,  
STOPPED ABOVE MEDICATION STILL HAVE SOME ELBOW PAIN

**Type:** MANUAL

**Status:** CURRENT

**Review Status:** Resolved-Response Edited

**Discrepancy:** Please add punctuation for clarity and also include year with dates.

**Internal Comment:** will do

**Resolution Type:** Data value changed. Disc no longer applicable.

**Resolution Text:**



**Document #: R281944213**

**Discrepancy ID:** 61266111

**Site:** CDB\_001

**Patient:** R1035

**Visit:** WEEK 15

**Visit Date:**

**CRF:** WEEK\_15

**Section:** STUDY DIARY

**Qualifying Value:** 15

**Field:** 6. I have experienced the following AEs

**Row:** 1

**Value Text:** 11-9-09 SORE THROAT/CHEST CONGESTION, START EQUATE ALLERGY RELIEF 10 MG 1 A DAY. 11-11-09 STOPPED TAKING ABOVE-THROAT & CHEST OK.

**Type:** MANUAL

**Status:** CURRENT

**Review Status:** Resolved-Response Edited

**Discrepancy:** Please enter verbatim per source.

**Internal Comment:**

**Resolution Type:** Due Diligence

**Resolution Text:**

# Deleted CRFs Report