Figure 3a. Adverse events analysis form for death, MI, stroke cases

RAND EPC EPHEDRA PROJECT ADVERSE EVENTS ANALYSIS FORM

Article ID:_____ Reviewer:_____

FDA Case Number: _____

Form Number: _____of_____(Fill out one form for each subject)

1. Does adverse event form report on ephedra or ephedrine?

CIRCLE ONE

Yes..... 1
No/ Unsure.....2 **(STOP)**

(IF NOT EPHEDRA/EPHEDRINE THEN STOP)

2. Are there adequate data available to analyze this report?

CIRCLE ONE

Yes..... 1
No .....2 **(STOP)**

(IF NOT ADEQUATE DATA THEN STOP-
MUST BE A SERIOUS ADVERSE EVENT AND PRODUCT SPECIFICALLY IDENTIFIED)

3. What additional sources of data are available?

CHECK ALL THAT APPLY AND/OR ENTER CODE

FDA affidavit ..... ☐ (01)
Medical records ..... ☐ (02)
Legal documents ..... ☐ (03)
Labels ..... ☐ (04)
Other (_____)☐ (96)
None of the above ..... ☐ (97)

4. What was the adverse event? **CHECK ALL THAT APPLY AND/OR ENTER CODE**

(Start codes at 40)

Death ..... ☐ (01)
MI..... ☐ (02)
CVA ..... ☐ (03)
Other serious adverse event (enter code: _____)
Other (_____)☐ (96)
None of the above ..... ☐ (97) **(STOP)**

5. IF MI, what procedures were done? **CHECK ALL THAT APPLY**

Coronary angiography..... ☐ (01)
Revascularization ..... ☐ (02)

6. IF MI, what was(were) the outcome of the procedure(s)?

No significant CAD ..... ☐ (01)
< 3V CAD..... ☐ (02)
3V or LMD..... ☐ (03)
Low LVEF (≤ 40%) ..... ☐ (04)

Figure 3a. Adverse events analysis form for death, MI, stroke cases (continued)
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7. IF STROKE, what is the outcome? **CIRCLE ONE**
   - Complete resolution 1
   - Minimally affected (still able to work) 2
   - Moderately affected (more than one limb) 3
   - Severely affected 4
   - Not described 8

8. Who completed the adverse events form? **CIRCLE ONE**
   - Physician / Health care provider 1
   - Subject 2
   - Subject surrogate 3
   - Government agency 4

9. What was the age of the subject on the date report was made?

   Enter number: _____ _____

10. What is the gender of the subject? **CIRCLE ONE**
    - Male 1
    - Female 2
    - Not described 8

11. Why was the subject taking the product?
    CHECK ALL THAT APPLY AND/OR ENTER CODE
    (Start codes at 4)
    - Weight loss ..... ☐ (01)
    - Improved athletic performance ..... ☐ (02)
    - Psychological effect ..... ☐ (03)
    - Other: … (enter code _____ , _____ , _____)
    - Not described ..... ☐ (98)

12. What was the source of the product? **CIRCLE ONE**
    - Retail market 1
    - Multi-level marketing/ out of home 2
    - Direct from manufacturer 3
    - Health care provider 4
    - Other (_____) 6
    - Not described 8

13. Was the product specifically identified? **CIRCLE ONE**
    - Yes 1
    - No 2

    (IF NO THEN SKIP TO QUESTION 18)

14. What is the common, proprietary, and/or scientific (genus, genus/species) name of the product? **ENTER CODE OR CIRCLE ONE OF THE BELOW**
    Code:_____
    - None 97
    - Not described 98
    - Not applicable 99

Figure 3a. Adverse events analysis form for death, MI, stroke cases (continued)
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15. Of which main constituents is the product made?

ENTER CODE FOR EACH OR CIRCLE ONE OF THE BELOW

Code: _____ _____, _____ _____ , _____ , _____

None 97
Not described 98
Not applicable 99

16. Was chemical analysis on ephedra alkaloids data presented?

CIRCLE ONE

Yes 1
No 2
Not described 8
Not applicable 9

17. Please fill in the following information on dosage data.
This information is from **analysis: (ENTER THE NUMBER AND CODES IN THE APPROPRIATE BOXES.)**

Dosage data	Number	Unit (code)
Total daily dose of ephedrine alkaloids		
Single dose of ephedrine alkaloids		
Total daily dose of caffeine		
Ratio caffeine/ephedrine alkaloids	:	

Codes for units:

µg	1
mg	2
gm	3
$mgkg^{-1}$	4
ND	8
NA	9

18. Please fill in the following information on dosage data.
This information is from **label: (ENTER THE NUMBER AND CODES IN THE APPROPRIATE BOXES.)**

Dosage data	Number	Unit (code)
Total daily dose of ephedrine alkaloids		
Single dose of ephedrine alkaloids		
Total daily dose of caffeine		
Ratio caffeine/ephedrine alkaloids	:	

Codes for units:

µg	1
mg	2
gm	3
$mgkg^{-1}$	4
ND	8
NA	9

19. What was the duration of ephedrine use? **CIRCLE ONE**

<48 hours 1
2-13 days 2
14-60 days (acute) 3
>60 days (chronic) 4
Not described 8

Figure 3a. Adverse events analysis form for death, MI, stroke cases (continued)
RAND EPC EPHEDRA PROJECT ADVERSE EVENTS ANALYSIS FORM

20. What was the timing of the last ephedrine dose? **CIRCLE ONE**
    <6 hours 1
    6-24 hours 2
    >24 hours 3
    Not described 8

21. Was the product used again after first adverse event? **CIRCLE ONE**
    Yes 1
    No 2
    Not described 8
    Not applicable 9

22. If product was used again after first adverse event, did the adverse event reoccur? **CIRCLE ONE**
    Yes 1
    No 2
    Not described 8
    Not applicable 9

23. Was the subject actively involved in exercise at or immediately before the occurrence of the adverse event? **CIRCLE ONE**
    Yes 1
    No 2
    Not described 8
    Not applicable 9

24. Did form report on use of any other substances? **(CHECK ALL THAT APPLY AND ENTER CODE)**
    Caffeine (in addition to product) ..... ☐
    Illicit drugs: ..... ☐
    Code: _____ , _____ , _____ , _____ ,
    _____ , _____ , _____ , _____
    Other Herbs: ..... ☐
    Code: _____ , _____ , _____ , _____ ,
    _____ , _____ , _____ , _____
    Prescribed or OTC medication: ..... ☐
    Code: _____ , _____ , _____ , _____ ,
    _____ , _____ , _____ , _____
    Other substance: ..... ☐
    Code: _____ , _____ , _____ , _____ ,
    _____ , _____ , _____ , _____
    Not described ..... ☐
    None ..... ☐

Figure 3a. Adverse events analysis form for death, MI, stroke cases (continued)
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25. Which of the following conditions were evaluated?

CHECK ALL THAT APPLY AND/OR ENTER CODE
(Start codes at 15)

Pre-existing condition:	PRESENT	EXCLUDED
Asthma	☐	☐
CAD	☐	☐
DM	☐	☐
HTN	☐	☐
Obesity	☐	☐
Renal disease	☐	☐
Substance abuse	☐	☐
Syncope	☐	☐
Thyroid condition	☐	☐
TIA History	☐	☐
Other vascular disease (_____)	☐	☐
Rheumatological diseases	☐	☐
Other (Enter code: _____)	☐	☐
Other (Enter code: _____)	☐	☐
Other (Enter code: _____)	☐	☐
Other (Enter code: _____)	☐	☐
Other (Enter code: _____)	☐	☐
Other (Enter code: _____)	☐	☐

26. Was a drug screen performed? **(CIRCLE ONE)**
Yes.....1
No .....2 **(STOP)**

27. Results of **URINE** screen:
(start codes at 03) **(CHECK ALL THAT APPLY)**
No substance found..... ☐ (01)
Substance(s) found and identified: (Enter code(s)):

(_____ , _____ , _____ , _____ , _____ , _____)

Not described ..... ☐ (98)

28. Results of **BLOOD** screen:
(start codes at 03) **(CHECK ALL THAT APPLY)**
No substance found..... ☐ (01)
Substance(s) found and identified: (Enter code(s) below)
(_____ , _____ , _____ , _____ , _____ , _____)

Not described ..... ☐ (98)

END