

**Figure 3b. Adverse events analysis form for seizure cases
RAND EPC EPHEDRA PROJECT**

ADVERSE EVENTS ANALYSIS FORM

ID/ FDA Case Number: _____	Reviewer: _____
First Author: _____ (Last Name Only)	
Form Number: ____ of ____ (Fill out one form for each subject)	

1. Does this adverse event report use of ephedra or ephedrine?

CIRCLE ONE

Ephedra only 1
 No/ Unsure 2 (STOP)
 Ephedrine only 3
 Ephedra and Ephedrine 4
(IF NOT EPHEDRA/ OR EPHEDRINE THEN STOP)

2. Is a generalized (tonic-clonic) seizure reported as an adverse event (synonym = grandmal seizure)?

CIRCLE ONE

Yes 1
 No, another type of seizure is reported 2 (STOP)
 No, seizure unspecified is reported 3 (STOP)
 No, seizure is not reported as an adverse event 9 (STOP)
(IF NO SEIZURE REPORTED THEN STOP)

3. For which evaluations are results reported as part of the evaluation of the seizure?

CHECK ALL THAT APPLY

Serum electrolytes (must include Na)
 Calcium
 Magnesium
 Glucose
 CT/ MRI of head
 EEG
 Temperature

4. Were the following pre-existing conditions specifically mentioned as present or excluded?
 Pre-existing condition: **NOT DESCRIBED** **PRESENT** **EXCLUDED**
 Alcoholism
 Substance Abuse
 Seizure Disorder

5. What was the age of the subject on the date the report was made?
 Enter number: _____ (No Data = 99)

6. What is the gender of the subject?
 Male 1
 Female 2
 Not described 8

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7. Why was the subject taking the product?

(Start codes at 04)

(CHECK ALL THAT APPLY AND/OR ENTER CODE)

Weight loss..... (01)

Improved athletic performance (02)

Psychological effect (03)

Other:..... (enter code _____ , _____ , _____)

Not described (98)

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Product: _____ of _____

Description: _____

8. 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 applicable 99

9. Of which main constituents is the product made?
(ENTER CODE FOR EACH OR CIRCLE ONE OF THE BELOW)

Code: _____ , _____ , _____ , _____ , _____
 _____ , _____ , _____ , _____ , _____
 None..... 97
 Not applicable 99

10. Was chemical analysis on ephedra alkaloids data presented?
(CIRCLE ONE)

Yes 1
 No..... 2
 Ordered but not reported 3
 Not described 8
 Not applicable 9

11. 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)	Codes for units:	
Total daily dose of ephedrine alkaloids			µg	1
Single dose of ephedrine alkaloids			mg	2
Total daily dose of caffeine			gm	3
Ratio caffeine/ephedrine alkaloids		:	mgkg ⁻¹	4
			ND	8
			NA	9

12. 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)	Codes for units:	
Total daily dose of ephedrine alkaloids			µg	1
Single dose of ephedrine alkaloids			mg	2
Total daily dose of caffeine			gm	3
Ratio caffeine/ephedrine alkaloids		:	mgkg ⁻¹	4
			ND	8
			NA	9

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13. 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

14. What was the timing of the last ephedrine dose? **(CIRCLE ONE)**

- <6 hours 1
- 6-24 hours 2
- >24 hours 3
- Not described 8

15. Was/were the product(s) discontinued after problematic symptoms emerged?

(CIRCLE ONE)

- Yes 1
- No 2
- Not described 8
- Not applicable 9

16. If product(s) was/were used again after discontinuation, did the problematic symptoms reoccur? **(CIRCLE ONE)**

- Yes 1
- No 2
- Not described 8
- Not applicable 9

17. Did form report on use of any other substances?

(ENTER CODE OR CIRCLE)

Code: _____ , _____ , _____ , _____ , _____

- None 97
- Not described 98
- Not applicable 99

18. Which of the following conditions were evaluated?

(Start codes at 15)

(CHECK ALL THAT APPLY AND/OR ENTER CODE)

Pre-existing condition:

PRESENT EXCLUDED

- | | | | |
|--|--------------------------|-------|--------------------------|
| Asthma | <input type="checkbox"/> | | <input type="checkbox"/> |
| CAD | <input type="checkbox"/> | | <input type="checkbox"/> |
| DM | <input type="checkbox"/> | | <input type="checkbox"/> |
| HTN | <input type="checkbox"/> | | <input type="checkbox"/> |
| Obesity | <input type="checkbox"/> | | <input type="checkbox"/> |
| Prior psychiatric history | <input type="checkbox"/> | | <input type="checkbox"/> |
| Renal disease | <input type="checkbox"/> | | <input type="checkbox"/> |
| Syncope | <input type="checkbox"/> | | <input type="checkbox"/> |
| Thyroid condition | <input type="checkbox"/> | | <input type="checkbox"/> |
| TIA History | <input type="checkbox"/> | | <input type="checkbox"/> |
| Other vascular disease (_____) | <input type="checkbox"/> | | <input type="checkbox"/> |
| Rheumatological diseases | <input type="checkbox"/> | | <input type="checkbox"/> |
| Not described | <input type="checkbox"/> | (98) | |

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

20. 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)

21. 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