

**Figure 3c. Adverse events analysis form for psychiatric 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 there an adverse event? (CIRCLE ONE)
 - Yes 1
 - No 2 (STOP)

(IF NO ADVERSE EVENT THEN STOP)

3. Was the product specifically identified? (CIRCLE ONE)
 - Yes 1
 - No 2 (STOP)

(MUST BE A SERIOUS ADVERSE EVENT AND
 PRODUCT SPECIFICALLY IDENTIFIED OR STOP)

4. What was the adverse event? (CHECK ALL THAT APPLY AND/OR ENTER TEXT)
 - Psychosis (06)
 - Mania or severe agitation (07)
 - Severe depression (08)
 - Suicidal ideation (09)
 - Suicide attempt/ Suicide (146)
 - Hallucinations (138)
 - Other serious psychiatric events: (enter below)
 - _____ (.)
 - _____ (.)
 - _____ (.)
 - _____ (.)
 - Other non-serious event: _____) (96) (STOP)
 - None of the above (97) (STOP)

Figure 3c. Adverse events analysis form for psychiatric cases (continued)

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5. Is there a presence or history of the following conditions?

(CHECK ALL THAT APPLY AND/OR ENTER TEXT)

	PRESENCE	HISTORY (CODES)
Psychosis	<input type="checkbox"/>	<input type="checkbox"/> (01)
Mania or severe agitation.....	<input type="checkbox"/>	<input type="checkbox"/> (02)
Hallucinations.....	<input type="checkbox"/>	<input type="checkbox"/> (03)
Severe depression	<input type="checkbox"/>	<input type="checkbox"/> (04)
Suicide attempt	<input type="checkbox"/>	<input type="checkbox"/> (05)
Suicide ideation.....	<input type="checkbox"/>	<input type="checkbox"/> (06)
Schizophrenia	<input type="checkbox"/>	<input type="checkbox"/> (07)
Acute confusion.....	<input type="checkbox"/>	<input type="checkbox"/> (08)
Delusions	<input type="checkbox"/>	<input type="checkbox"/> (09)
Aggression/threatened violence.....	<input type="checkbox"/>	<input type="checkbox"/> (10)
Substance abuse	<input type="checkbox"/>	<input type="checkbox"/> (11)
Other conditions:		
_____	<input type="checkbox"/>	<input type="checkbox"/> ()
_____	<input type="checkbox"/>	<input type="checkbox"/> ()
_____	<input type="checkbox"/>	<input type="checkbox"/> ()
_____	<input type="checkbox"/>	<input type="checkbox"/> ()
_____	<input type="checkbox"/>	<input type="checkbox"/> ()
_____	<input type="checkbox"/>	<input type="checkbox"/> ()
_____	<input type="checkbox"/>	<input type="checkbox"/> ()
None described	<input type="checkbox"/>	(98)

6. What was the outcome of the event? (CHECK ALL THAT APPLY)

Death	<input type="checkbox"/>
Harm to self/others.....	<input type="checkbox"/>
Hospitalization	<input type="checkbox"/>
ER Visit	<input type="checkbox"/>
On-going adverse event/disability.....	<input type="checkbox"/>
Resolved	<input type="checkbox"/>
Other: _____	<input type="checkbox"/>
Not described	<input type="checkbox"/>

Figure 3c. Adverse events analysis form for psychiatric cases (continued)

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7. What was intervention was prescribed after adverse event occurred?

(CHECK ALL THAT APPLY)

- No procedure
- Discontinue Ephedra.....
- Change existing medication.....

- New medication.....
- Initiate/change frequency/intensity of outpatient visits...
- Hospitalization.....

- Involuntary hospitalization.....
- Legal action.....
- Not described.....
- Not applicable.....

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

Enter number: _____ (No Data=99)

9. What is the gender of the subject?

(CIRCLE ONE)

- Male..... 1
- Female..... 2
- Not described..... 8

10. Why was the subject taking the product?

(CHECK ALL THAT APPLY)

- Weight loss.....
- Improved athletic performance.....
- Psychological effect.....
- Addiction.....

- Other: _____
- Not described.....

11. Did report describe the use of any other substances or medications taken prior to/or during the event?

- _____ ()
- _____ ()
- _____ ()
- _____ ()
- _____ ()

None described..... 98

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12. What is the common, proprietary, and/or scientific (genus, genus/species) name of the product? (ENTER TEXT OR CIRCLE ONE BELOW)

- Name: _____ ()
- None 97
- Not described 98
- Not applicable 99

13. Of which main constituents is the product made? (Enter text or circle one below)

- _____ ()
- _____ ()
- _____ ()
- _____ ()
- _____ ()
- _____ ()
- _____ ()
- _____ ()
- _____ ()
- None 97
- Not described 98
- Not applicable 99

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

- Yes 1
- No 2
- Ordered but not presented 3
- Not described 8
- Not applicable 9

Figure 3c. Adverse events analysis form for psychiatric cases (continued)

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15. Please fill in the following information on dosage data.

This information is from **analysis:** (ENTER THE NUMBER AND UNITS IN THE APPROPRIATE BOXES.)

Dosage data	Number	Unit	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

16. This information is from **label:** (ENTER THE NUMBER AND UNITS IN THE APPROPRIATE BOXES.)

Dosage data	Number	Unit	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

17. What was the duration of ephedra/ephedrine use? (CIRCLE ONE)

- <48 hour 1
- 2-13 days 2
- 14-60 days (acute) 3
- >60 days (chronic) 4
- 60 days to 1 year 5
- Over 1 year 6
- Not described 8

18. What was the timing of the last ephedra/ephedrine dose?(CIRCLE ONE)

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

19. Was/were the product(s) discontinued after problematic symptoms emerged? (CIRCLE ONE)

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

Figure 3c. Adverse events analysis form for psychiatric cases (continued)

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20. 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

21. Was autopsy performed? (CIRCLE ONE)

- Yes 1
- No 2
- Not Applicable 9

22. Was drug screen performed? (CIRCLE ONE)

- Yes 1
- No 2 (STOP)

23. Results of URINE screen: (CHECK ALL THAT APPLY AND/OR ENTER TEXT)

No substance found (01)

Substance(s) found and identified:

- _____ ()
- _____ ()
- _____ ()
- _____ ()
- _____ ()
- _____ ()
- _____ ()

Not described (98)

21. Results of **BLOOD** screen:(check all that apply and/or enter text)

No substance found (01)

Substance(s) found and identified:

- _____ ()
- _____ ()
- _____ ()
- _____ ()
- _____ ()
- _____ ()
- _____ ()

Not described (98)

END