Figure 4. Brief data collection form for case reports

RAND EPC EPHEDRA PROJECT **BRIEF FORM FOR CASE REPORTS**

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. What was the adverse event? **CHECK ALL THAT APPLY**

Death…… ☐ (01)

Cardiovascular:

- Heart rate, >120 *or* <50 ☐ (02)
- Hypertension, Systolic >180 *or* Diastolic >105 ☐ (03)
- MI ☐ (04)
- Ventricular tachycardia/ fibrillation ☐ (05)
- Cardiac arrest ☐ (06)

Pulmonary:

- Respiratory arrest ☐ (07)

Neurological:

- TIA ☐ (08)
- CVA ☐ (09)
- Brain Hemorrhage, not CVA ☐ (10)
- Fainting / Loss of consciousness ☐ (11)
- Coma ☐ (12)
- Seizure ☐ (13)
- Paralysis ☐ (14)

Psychiatric:

- Severe depression ☐ (15)
- Hallucinations ☐ (16)
- Mania or severe agitation ☐ (17)
- Psychosis ☐ (18)
- Suicide ☐ (19)

Other adverse events:

- Changes in glucose <40 *or* >400 ☐ (20)
- Liver failure ALT/AST >200 ☐ (21)
- Rhabdomyolysis CPK >400 ☐ (22)
- Miscarriage ☐ (23)
- Serious renal event ☐ (25)
- Autonomic Hyperactivity ☐ (26)

None of the above ☐ (24)