

Figure 7. Metabolife record screener form

Case Number: _____	Reviewer: _____
Form Number: ____ of ____ (Fill out one form for each subject)	

1. Subject's age: _____ (Not Described =999)

2. What is the subject's gender? **(CIRCLE ONE)**
Male..... 1
Female 2
Not described/ Not reported 3

3. What was the adverse event? **(CHECK ALL THAT APPLY)**
No adverse event reported (01)
(IF NO ADVERSE EVENT THEN STOP.)
Death..... (02)
Cardiovascular:
Heart rate, >120 or <50..... (03)
Heart rate, 50-120, or not otherwise unspecified (04)
Hypertension, Systolic >180 or Diastolic >105 (05)
Hypertension, Systolic <180 or Diastolic <105, or
not otherwise specified (06)
Myocardial Infarction/ Heart Attack (07)
Cardiac Dysrhythmia, Other/ Palpitations (08)
Cardiac arrest..... (09)
Ventricular Tachycardia/ Fibrillation..... (10)
Chest Pain, not specified as MI (11)
Pulmonary:
Respiratory arrest..... (12)
Neurological:
Transient Ischemic Attack (13)
CVA/ Stroke, not known to be hemorrhage (14)
Brain Hemorrhage..... (15)
Fainting / Loss of consciousness (16)
Coma..... (17)
Seizure (18)
Psychiatric:
Depression (19)
Hallucinations (20)
Mania or severe agitation..... (21)
Psychosis (22)
Suicide attempt (23)
Autonomic Hyperactivity (includes: tremor, twitching,
jitteriness, insomnia, increased sweating, agitation,
nervousness, and irritability) (24)

Figure 7. Metabolife record screener form (continued)

3. What was the adverse event? **(CHECK ALL THAT APPLY)**
(continued)

Other adverse events:

- Changes in glucose <40 or >400 (25)
- Liver failure ALT/AST >200 (26)
- Liver abnormality, not otherwise specified (27)
- Rhabdomyolysis CPK >400 (28)
- Rhabdomyolysis, not otherwise specified (29)
- Miscarriage (30)
- Allergic Reaction (31)
- Anesthesia complication (32)
- Fatigue/Fever/ Chills (33)
- Abnormal lab values, not otherwise specified (34)

Other adverse events not already specified:

- Ear, Eye, Nose, or Throat (35)
- Respiratory System (36)
- Cardiovascular System (37)
- Gastrointestinal System (38)
- Hepatobiliary System (39)
- Musculoskeletal System (40)
- Genitourinary System (41)
- Gynecologic (includes breast and menstrual symptoms) (42)
- Sexual Dysfunction (43)
- Neurological System (includes headache) (44)
- Mental Health (45)
- Skin (includes Pruritis) (46)
- Hematologic System (47)
- Oncologic System (48)
- Other symptoms not specified above (49)

4. Did the adverse event result in a hospital stay (at least one night; do not include emergency room visits)? **(CIRCLE ONE)**

- Yes 1
- No/ No Data 2

5. Is there additional information (medical records or similar) available for more detailed review regarding past health history, current, problems, toxicology results, etc? **(CIRCLE ONE)**

- Yes 1
- No 2

END