C. Suspect medication(s)

1. Name (give labeled strength & metric label, if known)
   #1
   #2

2. Dose, frequency & route used
   #1
   #2

3. Therapy dates (if unknown, give duration)
   #1
   #2

4. Diagnosis for use (indication)
   #1
   #2

5. Event ablated after use stopped or dose reduced
   #1 yes no doesn't apply
   #2 yes no doesn't apply

6. Lot # (if known)
   #1
   #2

7. Exp. date (if known)
   #1
   #2

8. Event reappeared after reintroduction
   #1 yes no doesn't apply
   #2 yes no doesn't apply

9. NDC # — for product problems only (if known)
   —

10. Concomitant medical products and therapy dates (exclude treatment of event)

D. Suspect medical device

1. Brand name

2. Type of device

3. Manufacturer name & address

4. Operator of device
   health professional
   lay user/patient
   other

5. Expiration date
   (month/year)

6. Other #
   model #
catalog #
serial #
lot #

7. If implanted, give date
   (month/year)

8. If explanted, give date
   (month/year)

9. Device available for evaluation? (Do not send to FDA)
   yes no returned to manufacturer on

10. Concomitant medical products and therapy dates (exclude treatment of event)

E. Initial reporter

1. Name & address
   phone #

2. Health professional?
   yes no

3. Occupation

4. Initial reporter also sent report to FDA
   yes no unk