

MEDICAL DEVICE REPORTING ANNUAL USER FACILITY REPORT

PART 2 - SUMMARY OF EVENT

PART 2 INSTRUCTIONS

If photocopies of previously submitted FDA Form 3500A (MedWatch) are not provided for each MDR reportable event, complete one copy of the following for each MDR report submitted to FDA and/or the manufacturer during the calendar year covered by this Annual Report.

1. USER FACILITY EVENT REPORT NUMBER

____ - ____ - ____
(HCFA or FDA Provided No.) (Year) (Sequence No.)

2. WHERE WAS REPORT SUBMITTED? (Check all that apply)

FDA Manufacturer Distributor Other _____

3. MANUFACTURER INFORMATION

a. Name

b. Street Address

c. City

d. State

e. ZIP Code

f. Country/Postal Code (if not U.S.)

4. DEVICE INFORMATION

a. Brand Name

b. Common Name

c. Model Number

d. Serial Number

e. Lot Number

f. Catalog Number

5. BRIEF DESCRIPTION OF EVENT