DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service
Food and Drug Administration
Center for Devices and Radiological Health

INSTRUCTIONS FOR COMPLETING THE MEDICAL DEVICE REPORTING ANNUAL USER FACILITY REPORT, FORM FDA 3419

Under 21 CFR Part 803, the MDR regulation requires that user facilities submit an annual summary report to FDA of all reportable adverse events submitted to manufacturers or the FDA during a designated reporting period. The annual reports must be submitted by January 1 for reportable events that were filed in the previous calendar year, January 1 through December 31. An annual report is not required if there were no reportable events submitted during the applicable reporting period. The annual report must provide the following information:

PART 1

1. **REPORT PERIOD:** Enter the 4-digit calendar year in which the adverse event reports were filed.

2. **USER FACILITY ID (HCFA OR FDA PROVIDED NUMBER):** Provide the user facility HCFA or FDA provided number, which consists of the user facility's 10-digit Health Care Financing Administration (HCFA) number used for medical device reports or the number assigned by the FDA for reporting purposes.

3. **USER FACILITY INFORMATION:** In items 3a-f, provide the user facility name and complete address.

4. **USER FACILITY CONTACT INFORMATION:** In items 4a-g provide the name, complete address and telephone number of the individual designated as the facility's contact person responsible for reporting adverse events to FDA.

5. **TOTAL NUMBER OF REPORTS ATTACHED OR SUMMARIZED:** List the total number of reportable events that are attached or summarized.

> 5a-b: Enter the lowest and the highest user facility report number submitted during the reporting period. The report numbers consist of the HCFA or FDA provided number, the 4-digit calendar year in which the reports were submitted and the 4-digit sequence number assigned to the adverse event.

For each adverse event report listed in the range of numbers identified in items 5a and 5b, attach a photocopy of the completed MedWatch FDA Form 3500A or, alternatively, you may complete Part 2 of this form for each event.

6. **SIGNATURE OF CONTACT:** Signature of the contact person listed in item 4.

7. **DATE OF REPORT:** Enter the date that this report form is completed.

PART 2

- This section is only filled out for each reported adverse event, if a photocopy of the 3500A for the report is not attached.

1. **USER FACILITY EVENT REPORT NUMBER:** Enter the user facility HCFA or FDA provided number, the 4-digit calendar year in which the adverse event was reported and the 4-digit sequence number assigned to that individual adverse event.

2. **WHERE WAS REPORT SUBMITTED?:** Check all the boxes that would apply.

3. **MANUFACTURER INFORMATION:** In items 3a-f, provide the name and complete address of the manufacturer. If the manufacturer is unknown, enter "UNK" in item 3a. and skip to item 4.

4. DEVICE INFORMATION: Enter the applicable device information in items 4a-f, listing the brand name, common name, model, serial, lot and/or catalog number. Enter "NA" for any item that does not apply or enter "UNK" for any item that is not known.

5. **BRIEF DESCRIPTION OF EVENT:** Provide a brief narrative of the reported adverse event.

The requirement for semiannual reporting by user facilities under 21 CFR Part 803.33 of the MDR regulation was changed to an annual report requirement by the Food and Drug Administration Modernization Act (FDAMA) dated November 21, 1997. The effective date of this change took place on February 19, 1998. (Reference Federal Register Notice dated May 12, 1998, docket number 98N-0170).