ABBREVIATED INSTRUCTIONS FOR FDA FORM 3500A
SPECIFIC TO MEDICAL DEVICE REPORTING

GENERAL INSTRUCTIONS

1. Complete all sections and items that apply and type all entries.
2. Use the following codes when information is not available for any item: **NA** - not applicable; **NI** - no information yet but maybe later; **UNK** - unknown.
3. Enter dates in following format: **MM/DD/YY** (e.g., June 3, 1995 = 06/03/95. If exact date not known, provide best estimate. Use **YYYY** for year 2000 and beyond.
4. Enter the user facility report number or distributor report number and/or manufacturer report number in upper right corner of page 1. This has the format **NNNNNNNNNN-YYYY-XXXXX** where Ns represent the 10-character HCFA number of the user facility or the 7 digit registration or identification number of the

manufacturer or distributor; **YYYY** is the year of the report and **XXXXX** is the 4 or 5 digit sequence number of the report for the reporting year (see 21 CFR 803 or guidelines).
5. Attach a continuation page(s) when entries exceed allowed space and indicate the report section and block number on each page.
6. Use the coding manual to complete blocks F10, H3, & H6. Ordering information for the Coding Manual, Document Number 799, is available by FAX at (800) 899-0381 or (301) 827-0111.
7. If more than one patient was involved in the same event, complete section A and blocks B2, B5, B6, B7, D10, and F10 for each patient. Enter the corresponding patient identifier in each block.
8. If more than one suspect medical device is involved, complete section D for each. Complete section F for one device and blocks F9, F10, F13 and F14 for each additional device. Pair each section D with its corresponding section F by marking each as follows: "Device 1", "Device 2", etc.

SPECIFIC INSTRUCTIONS

A. Patient information

A1 Use an identifier, do not use patient's name or SSN.

A2 Give patient's age or best estimate and indicate the time unit used (years, months, days).

B. Adverse event or product problem

B1 Check box 1 if adverse event and/or box 2 if product problem. Adverse event is used when reporting a death or serious injury. Product problem is used for a malfunction that could lead to a death or serious injury if it were to recur.

B2 Check appropriate event outcome. Check "disability" if the device may have caused or contributed to a permanent injury or impairment.

B5 Provide a complete description of event. Do not use the name of any person or institution. If space is inadequate, use continuation sheet(s) as necessary.

D. Suspect medical device

D The Suspect Medical Device is the device that may have caused or contributed to the MDR reportable event or the device that malfunctioned. It is important that the device be properly identified and that all applicable information in this block be completed.

F. For use by user facility/distributor-devices only

F2 Use the same report number as used on page 1 (see item 4 of General Instructions).

F7 If follow-up report, record the user facility or distributor initial report number in block F2 and the sequence number of this follow-up in the blank after "follow-up", e.g., for first follow-up enter "1", for second enter "2." Do not repeat previously submitted information on a follow-up report.

F10 Enter up to 3 "patient" and 3 "device" codes that most accurately describe the event. Place only one code in each box. Patient codes indicate the effects that an event may have had on the patient, including signs, symptoms, syndromes, or diagnosis and device codes describe failures or issues related to the device that are encountered during the event.

G. All manufacturers

G1 Enter the full name and address of the manufacturer reporting site (contact office) including contact name. The name and address of the manufacturing site, if different, must also be included in this block.

G3 Check source of reported information. If "literature" is checked, attach a copy of the article (in English) and record the literature citation in block H10. Check the "study" box when reporting an RPS/DPS study or postapproval study.

G5-6 Not for medical device use.

G7 Check "5-day" if five-day report, "Initial" if first or initial submission, or "follow-up" if follow-up or supplemental submission. If follow-up report, do not repeat previously submitted information. Place manufacturer report number of initial report in block G9 and the follow-up sequence number on the blank line in block G7 after "follow-up".

G8 Not for medical device use.

H. Device manufacturers only

H3 If device was evaluated, be sure to attach an evaluation summary.

H5 If the question is not relevant to the device (e.g., an x-ray machine), check "no".

H6 Codes must be entered for conclusions even if the device was not evaluated.

H7 Check all that apply.

H10 Enter any additional information, evaluation, or clarification. Do not duplicate previous information.

H11 Provide the following additional, corrected or missing information, identifying each data item by the applicable block and item number:

(1) any information missing on the user facility or distributor report, including any missing or incomplete event codes required by block F10,

(2) information corrected on the user facility or distributor report form after verification, including any corrected event codes required by block F10

(3) for each event code provided by the user facility or distributor in block F10, a statement of whether the type of event represented by the code is addressed in the device labeling, e.g., code # 1738 - labeled, code # 1701 - not labeled, and

(4) an explanation of why any required information was not provided and the steps taken to obtain such information.