This guidance was written prior to the February 27, 1997 implementation of FDA's Good Guidance Practices, GGP's. It does not create or confer rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both. This guidance will be updated in the next revision to include the standard elements of GGP's.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
1350 Piccard Drive
Rockville MD 20850

Dear Medical Device Manufacturer:

This letter is being sent to all manufacturers who have reported adverse events as required by the Medical Device Reporting regulation (21 CFR 803) effective July 31, 1996 using FDA Form 3500A. We have noted some common reporting problems and are providing this information to you along with some suggestions that you may find useful.

BASELINE REPORTS

Please read and follow the "Instructions for Completing Form 3417, Medical Device Reporting Baseline Report". If you do not have this document, see the instructions in the last paragraph of this letter.

Common Problems:

1. Baseline report not submitted

   A baseline report must be filed with the initial 3500A report for that model of device and any new information must be updated at the time of annual registration in accordance with the attached instructions. If an existing baseline report cannot be identified based on the device identification information in the individual event report (FDA Form 3500A) then you will receive a letter requesting submission of a baseline report. You can avoid this by making sure (a) the device is properly identified when you submit an event report on Form 3500A, and (b) a baseline report has been submitted for the device identified in the event report.

2. Items left blank

   No item can be left blank other than Part 2, item 12 when the device is a preamendment device. If the device labeling does not contain a model number, catalog number, or other unique device identifier, then enter NA (for not applicable) in the item but each device must have at least one identifier, e.g., it must have a

model number or a catalog number or some other type of identifier that is unique for that particular device. A lot number or serial number can not be used because it does not uniquely identify all devices of a particular type or design (i.e., a unique device "model").

3. Multiple devices entered in same box (Part 2, items 2, 4, 5 and 6)

When reporting using the device family basis for reporting (see instructions), report only one device in Part 2, items 2 - 8. Report each additional member of the device family using the template attached to the instructions.

4. Incorrect reporting site registration number (Part 1, item 2b)

Make sure you have identified and use the proper registration number for the reporting site. If your reporting site does not have a registration number, then indicate that the site does not have a registration number and FDA will assign a pseudo registration number. All domestic reporting sites are required to register in accordance with 21 CFR 807. Foreign sites are encouraged to register but are not required to do so.

5. Device life not completed or partially completed (Part 2, item 11)

Complete all items in this section. Provide the shelf life in months. If you don't claim a shelf life, then check the "N/A" box (11a). If you claim a shelf life, indicate whether or not the shelf life is stated on the label (yes or no). Indicate the expected life in months (11b) or check "N/A" if expected life is not an applicable concept for your device or check "Not Established/Indefinite" if the concept of expected life is applicable but you have not established an expected life or it is indefinite. See 21 CFR 803.3(bb) and (i) for definitions.

MEDWATCH 3500A REPORTS

Please consult the "Instructions for Completing Form 3500A with Coding Manual for Form 3500A". If you do not have this document, see the instructions in the last paragraph of this letter.

Common Problems:

1. Items left blank

No items can be skipped other than Block F and Block F can be skipped only if the report was not based on a user facility or distributor report. If the report was based on a user facility or distributor report, then any information missing from the user facility or distributor report must be recorded in Block H11 with a cross reference to each applicable item in Blocks A through F of the form. If any item is not applicable, enter NA. If any item is not available at time of completion, enter NI. If any item is unknown and unlikely to ever be known, enter UNK. Provide in Block H11 the reason you were not able to obtain any required information and the steps taken to obtain the information. Failure to complete all applicable items or to provide them in H11 may result in your receipt of a follow-up letter asking for the information.

If information becomes available or needs to be corrected, use Form 3500A to provide the information and note in Block G7 that it is follow_up #1. Please note in Block H2 what type of follow-up information you are providing. Provide all the new information or information that needs to be corrected from the initial report in the appropriate portions of the form. You should only provide the additional or corrected information. Do not repeat information that has already been submitted.

2. More than one device reported in same report

   Manufacturers can report only <u>one</u> device per report. If there was more than one device involved in the event, prepare and submit a separate report for each device and assign a different manufacturer report number to each report.

3. Report number incorrect or not provided

   Be sure that you provide a valid and correct manufacturer report number. The number must consist of the registration number of the manufacturing site, the four digit calendar year and a five digit sequence number (e.g., 1234567-1997-00001). In lieu of the manufacturing site registration number you may use an FDA provided reporting number or use your reporting site registration number under one of the variances provided by CDRH. You may obtain a copy of these variances from the same location indicated below for obtaining the form instructions and coding manual.

   The calendar year should be based on the date you completed and submitted your report. The sequence number must start over with "00001" for the first report completed and submitted in a new calendar year.

4. Block B2 not completed when Block B1 is marked "Adverse event"

   Block B1 must be checked "Adverse event" when and only when a device related death or serious injury is being reported. If "Adverse event" is checked then one or more appropriate boxes in Block B2 must be checked. Do not use Block B2 unless you have checked "Adverse event" in Block B1.

5. Block B4 improperly used to record manufacturer's report date

   Block B4 is intended to be used to record the date the reported information was received from the initial reporter. It is not intended to be used as the manufacturer report date. Unfortunately, Form 3500A does not provide a place to record the date of the manufacturer's report. CDRH will use the postmark date as an indicator of submission date.

6. Error in basic device identification

   Be sure the device is properly identified in Block D with the correct model number and catalog number. If it is not correct on a user facility report, then provide the correct information in Block H11. The identifier must be recorded exactly as recorded in the corresponding baseline report. If not, the Center's computer will not be able to match the device with an existing baseline and you will receive a follow-up letter requesting submission of a baseline report on the device.

7. Submission of a disclaimer

Disclaimers are not needed on the 3500A form. A disclaimer has already been provided. If you wish to submit another disclaimer, then submit it with the first baseline report, not the 3500A form. If you wish to make any subsequent changes in your disclaimer, please include a cover letter with the new disclaimer, stating that you are submitting a new disclaimer.

8. Source of report not indicated properly (G3)

If you receive a user facility report on Form 3500A, then check "user facility" in Block G3. If not, do not check "user facility" in Block G3. If you obtain the reported information from a health care professional and it was not officially submitted by a user facility on Form 3500A, then check "health professional", not "user facility", in Block G3 even if the health care professional is located at a user facility.

Attach a copy of any completed Form 3500A received from a user facility or distributor to your report. Do not make corrections directly on the attached report. Make all corrections in Block H11.

9. Device evaluated but evaluation summary not attached (H3)

If you evaluate the device you are required not only to provide evaluation method and results codes, but to also attach a written evaluation summary.

10. Device evaluated but evaluation method and evaluation results codes not provided (H6)

If you evaluated the device or made an evaluation related to the device, then be sure to provide all appropriate evaluation method and result codes.

11. Evaluation conclusion codes not provided (H6)

An evaluation conclusion code(s) must always be provided, even if you did not evaluate the device and/or you could not reach a conclusion (in that case use code 67 - "No conclusion can be drawn").

If you need a copy of the "Instructions for Completing Form 3500A with Coding Manual for Form 3500A" or "Instructions for Completing Form 3417, Medical Device Reporting Baseline Report", please call the Reporting Systems Monitoring Team at 301-594-2735 or send a facsimile request to 301-827-0038. You may also submit a written request to: Reporting Systems Monitoring Team (HFZ-533). Office of Surveillance and Biometrics, CDRH, 1350 Piccard Drive, Rockville, MD 20850.

Sincerely yours.

Leighton W. Hansel
Division Director
Division of Surveillance Systems
Office of Surveillance and Biometrics
Center for Devices and Radiological Health