Food and Drug Administration, HHS

§ 803.52 If I am a manufacturer, what information must I submit in my individual adverse event reports?

You must include the following information in your reports, if known or reasonably known to you, as described in §803.50(b). These types of information correspond generally to the format of FDA Form 3500A:

(a) Patient information (Form 3500A, Block A). You must submit the following:
   (1) Patient name or other identifier;
   (2) Patient age at the time of event, or date of birth;
   (3) Patient gender; and
   (4) Patient weight.

(b) Adverse event or product problem (Form 3500A, Block B). You must submit the following:
   (1) Identification of adverse event or product problem;
   (2) Outcomes attributed to the adverse event (e.g., death or serious injury). An outcome is considered a serious injury if it is:
      (i) Life-threatening injury or illness;
      (ii) Disability resulting in permanent impairment of a body function or permanent damage to a body structure; or
      (iii) Injury or illness that requires intervention to prevent permanent impairment of a body structure or function;
   (3) Date of event;
   (4) Date of report by the initial reporter;
   (5) Description of the event or problem, including information on how and when the device was involved, nature of the problem, patient followup or required treatment, and any environmental conditions that may have influenced the event;
   (6) Description of relevant tests, including dates and laboratory data; and
   (7) Other relevant patient history including preexisting medical conditions.
§ 803.53 Device manufacturer information (Form 3500A, Block H). You must submit the following:

(a) Type of reportable event (death, serious injury, malfunction, etc.); 
(b) Type of followup report, if applicable (e.g., correction, response to FDA request, etc.);
(c) If the device was returned to you and evaluated by you, you must include a summary of the evaluation. If you did not perform an evaluation, you must explain why you did not perform an evaluation;
(d) Device manufacture date (month, day, year);
(e) Whether the device was labeled for single use;
(f) Evaluation codes (including event codes, method of evaluation, result, and conclusion codes) (refer to FDA MEDWATCH Medical Device Reporting Code Instructions);
(g) Whether remedial action was taken and the type of action;
(h) Whether the use of the device was initial, reuse, or unknown;
(i) Whether remedial action was reported as a removal or correction under section 519(f) of the act, and if it was, provide the correction/removal report number; and
(j) Your additional narrative; and/or
(k) Corrected data, including:
(i) Any information missing on the user facility report or importer report, including any event codes that were not reported, or information corrected on these forms after your verification;
(ii) For each event code provided by the user facility under §803.32(e)(10) or the importer under §803.42(e)(10), you must include a statement of whether the type of the event represented by the code is addressed in the device labeling; and
(iii) If your report omits any required information, you must explain why this information was not provided and the steps taken to obtain this information.

§ 803.53 If I am a manufacturer, in which circumstances must I submit a 5-day report?

You must submit a 5-day report to us, on Form 3500A or an electronic equivalent approved under §803.14, no later than 5 work days after the day that you become aware that:
(a) An MDR reportable event necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health. You may become aware of the need for remedial action from any information, including any trend analysis; or
(b) We have made a written request for the submission of a 5-day report. If