Food and Drug Administration, HHS

submit this information in a supplemental report under §803.56.

§ 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 a discussion of how 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.

(c) Device information (Form 3500A, Block D). You must submit the following:
   (1) Brand name;
   (2) Type of device;
   (3) Your name and address;
   (4) Operator of the device (health professional, patient, lay user, other); and
   (5) Expiration date;

   (6) The unique device identifier (UDI) that appears on the device label or on the device package;
   (7) Model number, catalog number, serial number, lot number, or other identifying number;
   (8) Date of device implantation (month, day, year);
   (9) Date of device explantation (month, day, year);
   (10) Whether the device was available for evaluation, and whether the device was returned to you, and if so, the date it was returned to you; and
   (11) Concomitant medical products and therapy dates. (Do not report products that were used to treat the event.)

(d) Initial reporter information (Form 3500A, Block E). You must submit the following:
   (1) Name, address, and phone number of the reporter who initially provided information to you, or to the user facility or importer;
   (2) Whether the initial reporter is a health professional;
   (3) Occupation; and
   (4) Whether the initial reporter also sent a copy of the report to us, if known.

(e) Reporting information for all manufacturers (Form 3500A, Block G). You must submit the following:
   (1) Your reporting office’s contact name and address and device manufacturing site;
   (2) Your telephone number;
   (3) Your report sources;
   (4) Date received by you (month, day, year);
   (5) Type of report being submitted (e.g., 5-day, initial, followup); and
   (6) Your report number.

(f) Device manufacturer information (Form 3500A, Block H). You must submit the following:
   (1) Type of reportable event (death, serious injury, malfunction, etc.);
   (2) Type of followup report, if applicable (e.g., correction, response to FDA request, etc);
   (3) 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;
   (4) Device manufacture date (month, day, year);
§ 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 you receive such a written request from us, you must submit, without further requests, a 5-day report for all subsequent events of the same nature that involve substantially similar devices for the time period specified in the written request. We may extend the time period stated in the original written request if we determine it is in the interest of the public health.

§ 803.56 If I am a manufacturer, in what circumstances must I submit a supplemental or followup report and what are the requirements for such reports?

If you are a manufacturer, when you obtain information required under this part that you did not provide because it was not known or was not available when you submitted the initial report, you must submit the supplemental information to us within 1 month of the day that you receive this information. On a supplemental or followup report, you must:

(a) Indicate on the envelope and in the report that the report being submitted is a supplemental or followup report. If you are using FDA form 3500A, indicate this in Block Item H–2;

(b) Submit the appropriate identification numbers of the report that you are updating with the supplemental information (e.g., your original manufacturer report number and the user facility or importer report number of any report on which your report was based), if applicable; and

(c) Include only the new, changed, or corrected information in the appropriate portion(s) of the respective form(s) for reports that cross reference previous reports.

§ 803.58 Foreign manufacturers.

(a) Every foreign manufacturer whose devices are distributed in the United States shall designate a U.S. agent to be responsible for reporting in accordance with §807.40 of this chapter. The U.S. designated agent accepts responsibility for the duties that such designation entails. Upon the effective date of this regulation, foreign manufacturers shall inform FDA, by letter, of the name and address of the U.S. agent designated under this section and §807.40 of this chapter, and shall update this information as necessary. Such updated information shall be submitted to FDA, within 5 days of a