AUTHENTICATED
U.S. GOVERNMENT
INFORMATION
GPO

(4) Your contact person;
(5) Your contact person's telephone number;
(6) Date that you became aware of the event (month, day, year);
(7) Type of report (initial or followup). If it is a followup report, you must include the report number of your initial report;
(8) Date of your report (month, day, year);
(9) Approximate age of device;
(10) Event problem codes—patient code and device code (refer to FDA MEDWATCH Medical Device Reporting Code Instructions);
(11) Whether a report was sent to us and the date it was sent (month, day, year);
(12) Location where event occurred;
(13) Whether a report was sent to the manufacturer and the date it was sent (month, day, year); and
(14) Manufacturer name and address, if available.

Subpart E—Manufacturer Reporting Requirements

§ 803.50 If I am a manufacturer, what reporting requirements apply to me?

(a) If you are a manufacturer, you must report to us no later than 30 calendar days after the day that you receive or otherwise become aware of information, from any source, that reasonably suggests that a device that you market:
(1) May have caused or contributed to a death or serious injury; or
(2) Has malfunctioned and this device or a similar device that you market would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur.
(b) What information does FDA consider ''reasonably known'' to me?
(1) You must submit all information required in this subpart E that is reasonably known to you. We consider the following information to be reasonably known to you:
(i) Any information that you can obtain by contacting a user facility, importer, or other initial reporter;
(ii) Any information in your possession; or
(iii) Any information that you can obtain by analysis, testing, or other evaluation of the device.
(2) You are responsible for obtaining and submitting to us information that is incomplete or missing from reports submitted by user facilities, importers, and other initial reporters.
(3) You are also responsible for conducting an investigation of each event and evaluating the cause of the event. If you cannot submit complete information on a report, you must provide a statement explaining why this information was incomplete and the steps you took to obtain the information. If you later obtain any required information that was not available at the time you filed your initial report, you must 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);

(5) Expiration date;

(6) Model number, catalog number, serial number, lot number, or other identifying number;

(7) Date of device implantation (month, day, year);

(8) Date of device explantation (month, day, year);

(9) 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

(10) 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);

(5) Whether the device was labeled for single use;

(6) Evaluation codes (including event codes, method of evaluation, result, and conclusion codes) (refer to FDA MEDWATCH Medical Device Reporting Code Instructions);

(7) Whether remedial action was taken and the type of action;

(8) Whether the use of the device was initial, reuse, or unknown;

(9) 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

(10) Your additional narrative; and/or

(11) 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