(11) Concomitant medical products and therapy dates. (Do not report products that were used to treat the event.)

(d) Initial reporter information (Form FDA 3500A, Block E). You must submit the following:

(1) Name, address, and telephone 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 FDA 3500A, Block G). You must submit the following:

(1) Your reporting office's contact name and address and device manufacturing site;

(2) Your contact person's telephone number;

(3) Your report sources;

(4) Date received by you (month, day, year);

(5) PMA/510k Number and whether or not the product is a combination product;

(6) Type of report being submitted (e.g., 5-day, initial, followup); and

(7) Your report number.

(f) Device manufacturer information (Form FDA 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 Federal Food, Drug, and Cosmetic 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.

[79 FR 8846, Feb. 14, 2014, as amended at 80 FR 10587, Feb. 27, 2015]

§ 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 with the information required by § 803.52 in accordance with the requirements of § 803.12(a) 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.