

§ 803.53

(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 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.

21 CFR Ch. I (4–1–08 Edition)

§ 803.55 If I am a manufacturer, in what circumstances must I submit a baseline report, and what are the requirements for such a report?

(a) You must submit a baseline report for a device when you submit the first report under §803.50 involving that device model. Submit this report on FDA Form 3417 or an electronic equivalent approved under §803.14.

(b) You must update each baseline report annually on the anniversary month of the initial submission, after the initial baseline report is submitted. Report changes to baseline information in the manner described in §803.56 (i.e., include only the new, changed, or corrected information in the appropriate portion(s) of the report form). In each baseline report, you must include the following information:

(1) Name, complete address, and establishment registration number of your reporting site. If your reporting site is not registered under part 807, we will assign a temporary number for use in MDR reporting until you register your reporting site in accordance with part 807. We will inform you of the temporary MDR reporting number;

(2) FDA registration number of each site where you manufacture the device;

(3) Name, complete address, and telephone number of the individual who you have designated as your MDR contact, and the date of the report. For foreign manufacturers, we require a confirmation that the individual submitting the report is the agent of the manufacturer designated under §803.58(a);

(4) Product identification, including device family, brand name, generic name, model number, catalog number, product code, and any other product identification number or designation;

(5) Identification of any device that you previously reported in a baseline report that is substantially similar (e.g., same device with a different model number, or same device except for cosmetic differences in color or shape) to the device being reported. This includes additional identification of the previously reported device by model number, catalog number, or other product identification, and the date of the baseline report for the previously reported device;

(6) Basis for marketing, including your 510(k) premarket notification number or PMA number, if applicable, and whether the device is currently the subject of an approved postmarket study under section 522 of the act;

(7) Date that you initially marketed the device and, if applicable, the date on which you stopped marketing the device;

(8) Shelf life of the device, if applicable, and expected life of the device;

(9) The number of devices manufactured and distributed in the last 12 months and an estimate of the number of devices in current use; and

(10) Brief description of any methods that you used to estimate the number of devices distributed and the number of devices in current use. If this information was provided in a previous baseline report, in lieu of resubmitting the information, it may be referenced by providing the date and product identification for the previous baseline report.

EFFECTIVE DATE NOTE: At 61 FR 39869, July 31, 1996, in §803.55, paragraphs (b)(9) and (10) were stayed indefinitely.

§ 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 change in the designated agent information.

(b) U.S.-designated agents of foreign manufacturers are required to:

(1) Report to FDA in accordance with §§ 803.50, 803.52, 803.53, 803.55, and 803.56;

(2) Conduct, or obtain from the foreign manufacturer the necessary information regarding, the investigation and evaluation of the event to comport with the requirements of §803.50;

(3) Forward MDR complaints to the foreign manufacturer and maintain documentation of this requirement;

(4) Maintain complaint files in accordance with §803.18; and

(5) Register, list, and submit premarket notifications in accordance with part 807 of this chapter.

EFFECTIVE DATE NOTE: At 61 FR 38347, July 23, 1996, §803.58 was stayed indefinitely.

PART 806—MEDICAL DEVICES; REPORTS OF CORRECTIONS AND REMOVALS

Subpart A—General Provisions

- Sec.
- 806.1 Scope.
- 806.2 Definitions.

Subpart B—Reports and Records

- 806.10 Reports of corrections and removals.
- 806.20 Records of corrections and removals not required to be reported.