

§ 803.56

Changes to baseline information shall be reported 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). Baseline reports shall contain the following:

(1) Name, complete address, and registration number of the manufacturer's reporting site. If the reporting site is not registered, FDA will assign a temporary registration number until the reporting site officially registers. The manufacturer will be informed of the temporary registration number;

(2) FDA registration number of each site where the device is manufactured;

(3) Name, complete address, and telephone number of the individual who has been designated by the manufacturer as its MDR contact and date of the report. For foreign manufacturers, a confirmation that the individual submitting the report is the agent of the manufacturer designated under § 803.58(a) is required;

(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 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, including the 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 510(k) premarket notification number or PMA number, if applicable, and whether the device is currently the subject of an approved post-market study under section 522 of the act;

(7) Date the device was initially marketed and, if applicable, the date on which the manufacturer ceased marketing the device;

(8) Shelf life, 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

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(10) Brief description of any methods used to estimate the number of devices distributed and the method used to estimate 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 Supplemental reports.

When a manufacturer obtains information required under this part that was not provided because it was not known or was not available when the initial report was submitted, the manufacturer shall submit to FDA the supplemental information within 1 month following receipt of such information. In supplemental reports, the manufacturer shall:

(a) Indicate on the form and the envelope, that the reporting form being submitted is a supplemental report. If the report being supplemented is an FDA Form 3500A report, the manufacturer must select, in Item H-2, the appropriate code for the type of supplemental information being submitted;

(b) Provide the appropriate identification numbers of the report that will be updated with the supplemental information, e.g., original manufacturer report number and user facility report number, if applicable;

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

§ 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