

(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 re-

sponsibility 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 pre-market 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.
- 806.30 FDA access to records.
- 806.40 Public availability of reports.

AUTHORITY: 21 U.S.C. 352, 360, 360i, 360j, 371, 374.

SOURCE: 62 FR 27191, May 19, 1997, unless otherwise noted.

Subpart A—General Provisions

§ 806.1 Scope.

(a) This part implements the provisions of section 519(f) of the Federal Food, Drug, and Cosmetic Act (the act)