§ 803.33 If I am a user facility, what must I include when I submit an annual report?

(a) You must submit to us an annual report on FDA Form 3419, or electronic equivalent as approved by us under §803.14. You must submit an annual report by January 1, of each year. You must clearly identify your annual report as such. Your annual report must include:

(1) Your CMS provider number used for medical device reports, or the number assigned by us for reporting purposes in accordance with §803.3;

(2) Reporting year;

(3) Your name and complete address;

(4) Total number of reports attached or summarized;

(5) Date of the annual report and report numbers identifying the range of medical device reports that you submitted during the report period (e.g., 1234567890–2004-0001 through 1000);

(b) In lieu of submitting the information in paragraph (a)(7) of this section, you may submit a copy of FDA Form 3500A, or an electronic equivalent approved under §803.14, for each medical device report that you submitted to the manufacturer and/or to us during the reporting period.

(c) If you did not submit any medical device reports to manufacturers or us during the time period, you do not need to submit an annual report.