

### III.C.4. Request for Alternative Reporting Frequency

FDA is proposing to amend its postmarketing safety reporting regulations at §§ 310.305(c), 314.80(c), and 600.80(c) to state that, upon written notice, the agency may require, when appropriate, that manufacturers and

applicants submit postmarketing safety reports (*i.e.*, expedited, followup, or periodic safety reports) to FDA at times other than prescribed by the regulations (see tables 8 and 9 regarding proposed reporting frequencies for postmarketing safety reports). In most cases, FDA would not request alternative reporting

periods for these safety reports. In some cases, however, FDA may need to receive reports more frequently (*e.g.*, marketed product approved for a new indication, dosage form, or population) or less frequently (*e.g.*, product on the market for over 30 years with no new safety concerns identified).

TABLE 8.—PROPOSED REPORTING FREQUENCY FOR POSTMARKETING EXPEDITED SAFETY REPORTS

Submit as soon as possible	Submit within 5 calendar days	Submit within 7 calendar days	Submit within 15 calendar days	Submit within 30 calendar days	Submit within 45 calendar days
<ul style="list-style-type: none"> <li>Blood safety report—telephone (fatality) (D.12).<sup>1</sup></li> </ul>	<ul style="list-style-type: none"> <li>Individual case safety reports from contractors to manufacturer (D.9).</li> <li>Individual case safety reports from contractors and shared manufacturers to applicant (D.9).</li> </ul>	<ul style="list-style-type: none"> <li>Blood safety report—written (fatality) (D.12).</li> </ul>	<ul style="list-style-type: none"> <li>Serious and unexpected SADR report (D.1).</li> <li>Information sufficient to consider product administration changes (D.2).</li> <li>Always expedited report (D.4).</li> <li>Medication error report (D.5).</li> <li>15-day followup report (D.6).</li> </ul>	<ul style="list-style-type: none"> <li>30-day followup report (D.6).</li> </ul>	<ul style="list-style-type: none"> <li>Unexpected SADR with unknown outcome (D.3).</li> <li>Blood safety report—written (all serious SARs except fatalities) (D.12).</li> </ul>

<sup>1</sup> References in parentheses refer to location in section III of this document.

TABLE 9.—PROPOSED REPORTING FREQUENCY FOR POSTMARKETING PERIODIC SAFETY REPORTS

Persons with reporting responsibility	Submit every 6 months	Submit at 0.5, 1, 1.5, 2, 3, 4, and 5 years	Submit at 7.5 and 12.5 years	Submit at 10 years and every 5 years thereafter
Applicants with NDAs <sup>1</sup> or BLAs approved on or after 1/1/98 and applicants with approved pediatric use supplements.	Individual case safety reports—semiannual submission (E.4) <sup>2</sup> .	PSUR (E.2) .....	IPSR (E.3) .....	PSUR.
Applicants with NDAs or BLAs approved before 1/1/98.	Individual case safety reports—semiannual submission.	NA .....	TPSR (E.1) or IPSR.	TPSR or PSUR.

<sup>1</sup> Applicants with approved ANDAs would determine the type of postmarketing periodic safety report required to be submitted to FDA (*i.e.*, TPSR, PSUR, IPSR) and the frequency of submission for these reports based on the U.S. approval date of the application for the innovator NDA product (see section III.I of this document).

<sup>2</sup> References in parentheses refer to section III of this document.

FDA is also proposing to amend its postmarketing safety reporting regulations at §§ 314.80(c) and 600.80(c) to state that applicants who wish to submit postmarketing safety reports at times other than prescribed by these regulations may request a waiver for this purpose under §§ 314.90 or 600.90. This proposed revision does not represent a new provision, but rather provides a cross-reference to the existing waiver requirements under §§ 314.90 and 600.90.

FDA is also proposing to amend its postmarketing periodic safety reporting regulations at §§ 314.80(c)(2)(i) and 600.80(c)(2)(i) by removing the third and fourth sentences in these paragraphs. These sentences state that, upon written notice, FDA may request submission of periodic safety reports at different times than stated under §§ 314.80(c)(2)(i) and 600.80(c)(2)(i)

(*e.g.*, following the approval of a major supplement). FDA is proposing to remove these sentences because this information would now be stated under proposed §§ 314.80(c) and 600.80(c). This proposed revision represents an organizational change that clarifies that FDA may request a different time period for submission of not only postmarketing periodic safety reports, but also postmarketing expedited safety reports.

### III.C.5. Determination of Outcome, Minimum Data Set, and Full Data Set

Proposed §§ 310.305(c)(1)(i)(A), 314.80(c)(1)(i)(A), and 600.80(c)(1)(i)(A) would amend FDA's postmarketing safety reporting regulations to require that manufacturers and applicants immediately, upon initial receipt of an SADR report, determine the outcome for the SADR (whether the SADR is serious

or nonserious) and at least the minimum data set for the individual case safety report (*i.e.*, identifiable patient, identifiable reporter, suspect drug or biological product, and SADR). If the manufacturer or applicant is not able to immediately determine this information, active query would be required to be used by the manufacturer or applicant to obtain the information as soon as possible. FDA is proposing this change to clarify that timely acquisition of information is critical to determine whether an SADR must be submitted to FDA and, for those reactions that would be reported, whether the SADR would be submitted in a postmarketing expedited safety report or a postmarketing periodic safety report.

Proposed §§ 310.305(c)(1)(i)(A), 314.80(c)(1)(i)(A), and 600.80(c)(1)(i)(A) would also require manufacturers and applicants to immediately determine the