

TABLE 6.—PROPOSED POSTMARKETING EXPEDITED SAFETY REPORTS—Continued

Expedited Safety Report	Type of Information	Submission to FDA—Timeframe	Persons with Reporting Responsibility	Reference in Section III of this Document
Blood safety—oral or written.	Fatalities	As soon as possible.	Blood establishments.	D.12
Blood safety—written.	Fatalities	7 calendar days	
	All serious SARs except fatalities	45 calendar days.	

TABLE 7.—PROPOSED POSTMARKETING PERIODIC SAFETY REPORTS

Periodic safety report	Type of information	Submission to FDA—timeframe	Persons with reporting responsibility	Reference in section III of this document
Individual case safety reports—semiannual submission.	<ul style="list-style-type: none"> • Serious, expected SADR (domestic and foreign) and nonserious, unexpected SADR (domestic) if TPSR is submitted for the product.¹ • Serious, listed SADR (domestic and foreign) and nonserious, unlisted SADR (domestic) if PSUR is submitted for the product.² 	Every 6 months after U.S. approval of application. ³	Applicants	E.4
TPSR—for applications approved before January 1, 1998. ⁴	<ul style="list-style-type: none"> • Narrative summary and analysis of individual case safety reports • Increased frequency reports • Safety-related actions to be taken • Summary tabulations of individual case safety reports • History of safety-related actions taken • Location of safety records • Contact person information 	At 5, 7.5, 10, 12.5, and 15 years after U.S. approval of application and then every 5 years thereafter. ³	Applicants	E.1
PSUR—for applications approved on or after January 1, 1998.	Core Document <ul style="list-style-type: none"> • Introduction • Worldwide marketing status • Actions taken for safety reasons • Changes to CCSI • Worldwide patient exposure • Summary tabulations • Safety studies • Other information • Overall safety evaluation • Conclusion Appendices <ul style="list-style-type: none"> • Company core data sheet • U.S. labeling • Spontaneous reports from individuals other than health care professionals • SADR with unknown outcome • SADR from class action lawsuits • Lack of efficacy reports • Information on resistance to antimicrobial drug products • Medication errors • U.S. patient exposure • Location of safety records • Contact person 	Every 6 months after U.S. approval of application for 2 years, annually for the next 3 years, and then every 5 years thereafter. ³	Applicants	E.2
IPSR—for applications approved on or after January 1, 1998.	An “abbreviated PSUR;” same information as PSUR excluding summary tabulations.	At 7.5 and 12.5 years after U.S. approval of application. ³	Applicants	E.3

¹ Nonserious, expected SARs (domestic) and expected SARs with unknown outcome (domestic) would also be submitted for vaccines.

² Nonserious, listed SARs (domestic) and listed SARs with unknown outcome (domestic) would also be submitted for vaccines.

³ The data lock point for the report would be the month and day of the international birth date or any other month and day agreed on by the applicant and FDA. The submission date for the report would be within 60 calendar days of the data lock point.

⁴ A PSUR may be submitted in lieu of a TPSR if an applicant so desires.

Current §§ 310.305(c), 314.80(c), 314.98(b), and 600.80(c) provide mailing addresses for the submission of

postmarketing safety reports. FDA is proposing to remove the mailing addresses from §§ 310.305(c), 314.80(c),

314.98(b), and 600.80(c) because this information is provided in the draft guidance of 2001.