

(B) *Minimum information for reports of actual medication errors that do not result in an SAR.* For reports of actual medication errors that do not result in an SAR, an individual case safety report must be submitted to FDA even though the report does not contain a minimum data set (*i.e.*, does not have an SAR). These reports must contain at least an identifiable patient, an identifiable reporter, and a suspect biological product.

(C) *Minimum information for potential medication error reports.* For reports of potential medication errors, an individual case safety report must be submitted to FDA even though the report does not contain a minimum data set (*i.e.*, does not have an identifiable patient or an SAR). These reports must contain at least an identifiable reporter and a suspect biological product.

(iv) *Full data set.* For reports of serious SARs, always expedited reports (see paragraph (c)(2)(iv) of this section), and medication error reports (see paragraph (c)(2)(v) of this section), the applicant must submit a full data set. If a full data set is not available for the report, the applicant must use active query to obtain this information. If a full data set is not obtainable after active query, the applicant must:

(A) Submit all safety information, received or otherwise obtained, for the report;

(B) Indicate the reason(s) for its inability to acquire a full data set; and

(C) Document its efforts to obtain a full data set (*i.e.*, description of unsuccessful steps taken to obtain this information).

(v) *Serious SARs not initially reported by a health care professional.* For a serious SAR that was not initially reported to the applicant by a health care professional (*e.g.*, report from a consumer), the applicant must contact the health care professional associated with the care of the patient using active query to gather further medical perspective on the case and to acquire a full data set for the report. If the applicant is unable to contact the health care professional, it must include in the report for the serious SAR:

(A) The reason(s) for its inability to contact the health care professional; and

(B) A description of its efforts to contact the health care professional.

(vi) *Nonserious SARs.* For reports of nonserious SARs with a minimum data set, except for those resulting from a medication error, all safety information received or otherwise obtained by the applicant must be submitted to FDA even though information in addition to the minimum data set is not required to be acquired. Reports of nonserious SARs

resulting from a medication error require a full data set under paragraph (c)(1)(iv) of this section.

(2) *Postmarketing "expedited reports"*—(i) *Serious and unexpected SAR.* The applicant must report to FDA each SAR, received or otherwise obtained, that is both serious and unexpected, whether foreign or domestic, as soon as possible, but in no case later than 15 calendar days after receipt by the applicant of the minimum data set for the serious, unexpected SAR. If a full data set is not available for the serious and unexpected SAR report at the time of initial submission of the report to FDA, the applicant must submit the information required under paragraph (c)(1)(iv) of this section and also submit a 30-day followup report as required by paragraph (c)(2)(vi) of this section.

(ii) *Information sufficient to consider product administration changes.* The applicant must also report to FDA information, received or otherwise obtained, whether foreign or domestic, that would be sufficient, based upon appropriate medical judgment, to consider changes in product administration. The applicant must submit this information to FDA as soon as possible, but in no case later than 15 calendar days after determination by the applicant that the information qualifies for expedited reporting. Examples of such information include any significant unanticipated safety finding or data in the aggregate from an in vitro, animal, epidemiological, or clinical study, whether or not conducted under an investigational new drug application (IND), that suggests a significant human risk, such as reports of mutagenicity, teratogenicity, or carcinogenicity, or reports of a lack of efficacy with a biological product used in treating a life-threatening or serious disease. The applicant must maintain a record of its efforts to determine whether the information required to be reported under this paragraph qualifies for expedited reporting.

(iii) *Unexpected SAR with unknown outcome.* The applicant must also report to FDA each SAR that is unexpected and for which the determination of an outcome is unattainable (*i.e.*, SAR with unknown outcome) within 45 calendar days after initial receipt by the applicant of the minimum data set for the unexpected SAR. The applicant must document in the expedited report the reason(s) for the inability to determine the outcome.

(iv) *Always expedited report.* (A) The applicant must also report to FDA each SAR, received or otherwise obtained, whether foreign or domestic, that is the

subject of an always expedited report. These reports must be submitted to FDA as soon as possible, but in no case later than 15 calendar days after receipt by the applicant of the minimum data set for the report. The following medically significant SARs, which may jeopardize the patient or subject and/or require medical or surgical intervention to treat the patient or subject, are subject to an always expedited report:

- (1) Congenital anomalies,
- (2) Acute respiratory failure,
- (3) Ventricular fibrillation,
- (4) Torsades de pointes,
- (5) Malignant hypertension,
- (6) Seizure,
- (7) Agranulocytosis,
- (8) Aplastic anemia,
- (9) Toxic epidermal necrolysis,
- (10) Liver necrosis,
- (11) Acute liver failure,
- (12) Anaphylaxis,
- (13) Acute renal failure,
- (14) Sclerosing syndromes,
- (15) Pulmonary hypertension,
- (16) Pulmonary fibrosis,
- (17) Confirmed or suspected

transmission of an infectious agent by a marketed drug or biological product,

(18) Confirmed or suspected endotoxin shock, and

(19) Any other medically significant SAR that FDA determines to be the subject of an always expedited report (*i.e.*, may jeopardize the patient or subject and/or require medical or surgical intervention to treat the patient or subject).

(B) SARs that are the subject of an always expedited report must be submitted to FDA whether unexpected or expected and whether or not the SAR leads to a serious outcome. If a full data set is not available for an always expedited report at the time of initial submission of the report to FDA, the applicant must submit the information required under paragraph (c)(1)(iv) of this section and also submit a 30-day followup report as required by paragraph (c)(2)(vi) of this section.

(v) *Medication error*—(A) *Actual medication error.* The applicant must also submit to FDA each domestic report of an actual medication error, received or otherwise obtained, as soon as possible, but in no case later than 15 calendar days after receipt by the applicant of the minimum data set for a report of an SAR or, if an SAR does not occur, the minimum information described under paragraph (c)(1)(iii)(B) of this section (*i.e.*, identifiable patient, identifiable reporter, and suspect biological product).

(B) *Potential medication error.* The applicant must also submit to FDA each domestic report of a potential