

least an identifiable patient, an identifiable reporter, and a suspect drug 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 SADR). These reports must contain at least an identifiable reporter and a suspect drug product.

(iv) *Full data set.* For reports of serious SADRs, 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 SADRs not initially reported by a health care professional.* For a serious SADR 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 SADR:

(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 SADRs.* For reports of nonserious SADRs 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 SADRs 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 SADR.* The applicant must report to FDA each SADR, 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 SADR. If a full data set is not available for the serious and unexpected SADR at the time of initial submission of the expedited 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 drug 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 SADR with unknown outcome.* The applicant must also report to FDA each SADR that is unexpected and for which the determination of an outcome is unattainable (*i.e.*, SADR with unknown outcome) within 45 calendar days after initial receipt by the applicant of the minimum data set for the unexpected SADR. 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 SADR, 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 SADRs, 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 pointe,
- (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 SADR 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) SADRs that are the subject of an always expedited report must be submitted to FDA whether unexpected or expected and whether the SADR leads to a serious outcome or not. 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 errors—(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 SADR or, if an SADR does not occur, the minimum information described under paragraph (c)(1)(iii)(B) of this section (*i.e.*, identifiable patient, identifiable reporter, and suspect drug product).

(B) *Potential medication error.* The applicant must also submit to FDA each domestic report of a potential 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 information described under paragraph (c)(1)(iii)(C) of this section (*i.e.*, identifiable reporter and suspect drug product).