

(C) *Full data set.* If a full data set is not available for an actual or potential medication error 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.

(vi) *The 30-day followup report.* The applicant must use active query to obtain additional information for any expedited report under paragraphs (c)(2)(i), (c)(2)(iv), and (c)(2)(v) of this section that does not contain a full data set and must submit a followup report to FDA within 30 calendar days after initial submission of the expedited report to FDA by the applicant. If a full data set is still not obtainable, the 30-day followup report must contain the information required under paragraph (c)(1)(iv) of this section. Any new safety information in the 30-day followup report must be highlighted. Any new information, received or otherwise obtained, after submission of a 30-day followup report must be submitted to FDA as a 15-day followup report under paragraph (c)(2)(vii) of this section.

(vii) *The 15-day followup report.* The applicant must report to FDA any new information, received or otherwise obtained, for any expedited or followup report (except for initial expedited reports under paragraphs (c)(2)(i), (c)(2)(iv), and (c)(2)(v) of this section that do not contain a full data set) within 15 calendar days of initial receipt of the new information by the applicant. Expedited reports under paragraphs (c)(2)(i), (c)(2)(iv), and (c)(2)(v) of this section that do not contain a full data set at the time of initial submission of the report to FDA are subject to the 30-day followup reporting requirements under paragraph (c)(2)(vi) of this section rather than the 15-day followup reporting requirements under this paragraph.

(viii) *Supporting documentation.* (A) If the patient dies, the applicant must submit a copy of the autopsy report to FDA, if it is available. If an autopsy report is not available, the applicant must submit a death certificate to FDA. If an autopsy report becomes available after the applicant has submitted a death certificate to the agency, the autopsy report must be submitted to FDA. If the patient was hospitalized, the applicant must submit a copy of the hospital discharge summary to FDA, if it is available. If any of these documents is not in English, the document must be accompanied by an English translation. Applicants must use active query to obtain these documents. These documents must be submitted to FDA as

15-day followup reports (see paragraph (c)(2)(vii) of this section) within 15 calendar days of initial receipt of the document by the applicant. If these documents are not submitted to FDA in a 15-day followup report within 3 months after submission of the initial expedited report for the death or hospitalization, the agency will assume that active query by the applicant has not resulted in access to these documents. In this case, a record of the reason(s) for the lack of such documentation and the effort that was made to obtain the documentation must be maintained by the applicant.

(B) Each expedited report must contain in the narrative a list of other relevant documents (e.g., medical records, laboratory results, data from studies) for the report that are maintained by the applicant. When appropriate, FDA may require an applicant to submit copies of one or more of these documents to the agency within 5 calendar days after receipt of the request.

(ix) *Scientific literature.* An expedited report based on information from the scientific literature applies only to reports found in scientific and medical journals. These expedited reports must be accompanied by a copy of the published article.

(x) *Submission of safety reports by contractors.* (A) Contractors must submit to the applicant safety reports of any SADR or medication errors for the applicant's drug product, obtained or otherwise received, within 5 calendar days of initial receipt of the report by the contractor. The contractor must submit a safety report for an SADR to the applicant even if the report does not contain a minimum data set. Upon receipt of the safety report from the contractor, the applicant must comply with the postmarketing safety reporting requirements of this section.

(B) A contract between the applicant and a contractor must specify the postmarketing safety reporting responsibilities of the contractor. The applicant is responsible for assuring that the contractors of its drug products comply with these postmarketing safety reporting responsibilities.

(C) The contractor must maintain a record of each submission to the applicant under paragraph (c)(2)(x)(A) of this section that includes:

- (1) A copy of each safety report;
- (2) The date the report was initially received by the contractor;
- (3) The date the report was submitted to the applicant; and
- (4) The name and address of the applicant.

(D) The recordkeeping, written procedures and disclaimer provisions under paragraphs (f), (g), and (i) of this section apply to contractors.

(xi) *Report identification.* Each expedited report submitted to FDA under paragraphs (c)(2)(i) through (c)(2)(vii) of this section must bear prominent identification as to its contents, e.g., "expedited report—serious and unexpected SADR," "expedited report—30-day followup." Each type of report (e.g., serious and unexpected SADR reports, 30-day followup reports) must be submitted to FDA under separate cover. Reports of medication errors must indicate whether the error is actual or potential and, if actual, whether a serious SADR, nonserious SADR, or no SADR occurred, e.g., "expedited report—actual medication error—nonserious SADR," "Expedited report—potential medication error."

(3) *Postmarketing periodic safety reports.* The applicant must submit postmarketing periodic safety reports under this section (i.e., TPSRs, PSURs, IPSRs, individual case safety reports—semiannual submission) to FDA within 60 calendar days after the data lock point for the report. The applicant must include a cover letter containing a list of the new drug application number(s) (i.e., NDA number(s)) for the human drug product(s) covered by the postmarketing periodic safety report. The international birth date for combination products is the international birth date of the human drug product containing the drug substance most recently approved for marketing.

(i) *Traditional periodic safety reports (TPSRs).* An applicant holding an application for a human drug product approved under section 505(c) of the act before January 1, 1998, must submit either a PSUR as prescribed under paragraph (c)(3)(ii) of this section or a TPSR as described under this paragraph every 5 years after U.S. approval of the application. In addition, these applicants must submit either an IPSR as described under paragraph (c)(3)(iii) of this section or a TPSR as described under this paragraph 7.5 years and 12.5 years after U.S. approval of the application. The data lock point for the TPSR, PSUR, or IPSR is the month and day of the international birth date of the drug product or any other month and day agreed on by the applicant and FDA. Each TPSR must contain:

(A) *Summary.* This section of the TPSR includes:

(1) A narrative summary and analysis of serious, expected SADRs and nonserious, unexpected SADRs