

accompanied by an English translation. Manufacturers 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) in this section) within 15 calendar days of initial receipt of the document by the manufacturer. 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 manufacturer 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 manufacturer.

(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 manufacturer. When appropriate, FDA may require a manufacturer 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) *Attachments.* Each expedited report must be accompanied by a copy of the current U.S. labeling for the drug product and a list of current addresses where all safety reports and other safety-related records for the drug product are maintained by manufacturers and contractors.

(xi) *Submission of safety reports by contractors.* (A) Contractors must submit to the manufacturer safety reports of any SADRs or medication errors for the manufacturer'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 manufacturer even if the report does not contain a minimum data set. Upon receipt of the safety report from a contractor, the manufacturer must comply with the postmarketing safety reporting requirements of this section.

(B) A contract between the manufacturer and a contractor must specify the postmarketing safety reporting responsibilities of the contractor. The manufacturer is responsible for ensuring 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 manufacturer under paragraph (c)(2)(xi)(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 manufacturer; and
- (4) The name and address of the manufacturer.

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

(xii) *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—§ 310.305—serious and unexpected SADR," "expedited report—§ 310.305—30-day followup report." 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—§ 310.305—actual medication error—nonserious SADR," "expedited report—§ 310.305—potential medication error."

(d) *Reporting format.* (1)(i) Except as provided in paragraphs (d)(1)(ii), (d)(1)(iv), and (d)(5) of this section, the manufacturer must complete an FDA Form 3500A for each individual case safety report of an SADR. Reports based on information about individual cases or case series in the scientific literature must be submitted on an FDA Form 3500A(s).

(ii) Foreign SADRs may be submitted either on an FDA Form 3500A or, if preferred, on a CIOMS I form.

(iii) Each domestic report of an actual or potential medication error must be submitted on an FDA Form 3500A.

(iv) Reports of overall findings or data in the aggregate from published and unpublished in vitro, animal, epidemiological, or clinical studies must be submitted in a narrative format.

(2) Each SADR in an individual case safety report must be coded on the FDA Form 3500A or CIOMS I form using the appropriate "preferred term" in the latest version of MedDRA (the medical dictionary for regulatory activities) in use at the time the manufacturer becomes aware of the individual case safety report. For individual case safety reports of medication errors, the report

must be coded both as a medication error and, if applicable, with the preferred term for any SADRs associated with the medication error.

(3) Each completed FDA Form 3500A or CIOMS I form should refer only to an individual case.

(4) Each completed FDA Form 3500A or CIOMS I form must include the name and telephone number (and fax number and e-mail address, if available) for the licensed physician responsible for the content and medical interpretation of the data contained within the form (i.e., contact person for the company).

(5) Instead of using FDA Form 3500A, the manufacturer may use a computer-generated facsimile of FDA Form 3500A provided that it is readable, includes appropriate identifying information, and contains all the elements (i.e., format, sections, blocks, titles, descriptors within blocks, text for disclaimer) of FDA Form 3500A in the identical enumerated sequence of the form. For individual case safety reports in which no suspect medical device is involved, a one-page FDA Form 3500A is acceptable.

(e) *Patient privacy.* The names and addresses of individual patients should not be included in reports under this section; instead, the manufacturer and its contractors should assign a unique code to each report, preferably not more than eight characters (i.e., numbers/letters) in length. The name of the reporter from whom the information was received should be included. Names of patients, individual reporters, health care professionals, hospitals, and geographic identifiers in safety reports are not releasable to the public under FDA's public information regulations in part 20 of this chapter.

(f) *Recordkeeping.* (1) Each manufacturer must maintain for a period of 10 years records of all safety information pertaining to its drug product, received or otherwise obtained, including raw data, any correspondence relating to the safety information, and any reports of SADRs or medication errors not submitted to FDA. The manufacturer must also retain for a period of 10 years any records required to be maintained under this section. When appropriate, FDA may require a manufacturer to submit any or all of these records to the agency within 5 calendar days after receipt of the request.

(2) Manufacturers and packers may retain the records required in paragraph (f)(1) of this section as part of its complaint files maintained under § 211.198 of this chapter.

(3) Manufacturers must permit any authorized FDA employee, at all