

III.D.5. Medication Errors

Proposed §§ 310.305(c)(2)(v)(A), 314.80(c)(2)(v)(A), and 600.80(c)(2)(v)(A) would require that each domestic report of an actual medication error, received or otherwise obtained, be submitted to the agency as soon as possible, but in no case later than 15 calendar days after receipt by the manufacturer ("applicant" for proposed §§ 314.80(c)(2)(v)(A) and 600.80(c)(2)(v)(A)) of the minimum data set for a report of an SADR or, if an SADR does not occur, the minimum information for the report as described in section III.C.5 of this document (*i.e.*, an identifiable patient, an identifiable reporter, and a suspect drug or biological product). For postmarketing safety reporting purposes, all reports of medication errors would be considered unexpected. FDA is proposing this new type of expedited report to protect public health.

Proposed §§ 310.305(c)(2)(v)(B), 314.80(c)(2)(v)(B), and 600.80(c)(2)(v)(B) would require that reports of potential medication errors, received or otherwise obtained, be submitted to the agency as soon as possible, but in no case later than 15 calendar days after receipt by the manufacturer ("applicant" for proposed §§ 314.80(c)(2)(v)(B) and 600.80(c)(2)(v)(B)) of the minimum information described in section III.C.5 of this document (*i.e.*, an identifiable reporter and a suspect drug or biological product). FDA is proposing submission of this information to the agency in an expedited manner to attempt to prevent actual medication errors.

Proposed §§ 310.305(c)(2)(v)(C), 314.80(c)(2)(v)(C), and 600.80(c)(2)(v)(C) state that 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, manufacturers and applicants would submit the information required under proposed §§ 310.305(c)(1)(iv), 314.80(c)(1)(iv) and 600.80(c)(1)(iv) as described in section III.C.5 of this document and also submit a 30-day followup report as described in section III.D.6 of this document. FDA is proposing this action to clarify the importance of acquiring complete information for reports of medication errors.

III.D.6. Followup Reports

Current postmarketing expedited safety reporting regulations at §§ 310.305(c)(2), 314.80(c)(1)(ii), and 600.80(c)(1)(ii) require persons subject to these regulations to promptly investigate all serious, unexpected adverse drug experiences that are the

subject of expedited reports and to submit followup reports within 15 calendar days of receipt of new information or as requested by FDA. If additional information is not obtainable, records should be maintained of the unsuccessful steps taken to seek additional information. Thus, followup reports are currently only required to be submitted to FDA if requested by the agency or if new information is obtained or otherwise received by the manufacturer or applicant for an adverse drug experience previously reported to FDA.

In this rulemaking, FDA continues to require submission of these followup reports. In addition, as described in the following paragraph, a 30-day followup report would be required to be submitted in certain cases (*i.e.*, initial serious and unexpected SADR reports, always expedited reports and medication error reports that do not contain a full data set). If a 30-day followup report is required and no new information is available for the report, then the manufacturer or applicant would still be required to submit the 30-day followup report, indicate in the report that no new information was available and include a description of the reason(s) for its inability to acquire complete information and its efforts to obtain complete information. In all other cases, if there is no new information to report to FDA on a previously submitted SADR no followup report would be required to be submitted to the agency.

Proposed §§ 310.305(c)(2)(vi), 314.80(c)(2)(vi), and 600.80(c)(2)(vi) would require manufacturers and applicants to use active query to obtain additional information for any serious and unexpected SADR submitted to FDA in an expedited report under proposed §§ 310.305(c)(2)(i), 314.80(c)(2)(i), and 600.80(c)(2)(i) that does not contain a full data set. The proposed amendment would also require these persons to use active query to obtain additional information for any always expedited report under proposed §§ 310.305(c)(2)(iv), 314.80(c)(2)(iv), and 600.80(c)(2)(iv) or any medication error report under proposed §§ 310.305(c)(2)(v), 314.80(c)(2)(v), and 600.80(c)(2)(v) that does not contain a full data set. This information would be submitted to the agency in a followup report within 30 calendar days after initial submission of the expedited report to FDA by the manufacturer or applicant (30-day followup report). This proposed amendment would provide the agency with timely acquisition of more complete information for SADRs

and medication errors that are the subject of these reports.

Proposed §§ 310.305(c)(2)(vi), 314.80(c)(2)(vi), and 600.80(c)(2)(vi) would also state that:

* * * 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.

This proposed amendment would clarify the information that would be required in a 30-day followup report if a full data set is still not available for the report. It would also clarify that FDA would require a 15-day followup report, as described in the paragraphs that follow, for any new information obtained or otherwise received for the report after submission of the 30-day followup report. The proposed amendment would ensure that manufacturers and applicants would exercise due diligence to obtain complete information for SADRs that are the subject of 30-day followup reports.

Proposed §§ 310.305(c)(2)(vii), 314.80(c)(2)(vii), and 600.80(c)(2)(vii) would amend §§ 310.305(c)(2), 314.80(c)(1)(ii), and 600.80(c)(1)(ii) to clarify that manufacturers and applicants must submit 15-day followup reports to FDA of any new information received or otherwise obtained for any expedited or followup report (except for initial expedited reports under proposed §§ 310.305(c)(2)(i), (c)(2)(iv), and (c)(2)(v), 314.80(c)(2)(i), (c)(2)(iv), and (c)(2)(v), and 600.80(c)(2)(i), (c)(2)(iv), and (c)(2)(v) that do not contain a full data set) within 15 calendar days of initial receipt of new information by the manufacturer or applicant. Proposed §§ 310.305(c)(2)(vii), 314.80(c)(2)(vii), and 600.80(c)(2)(vii) would also state that:

* * * 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.

Thus, 15-day followup reports would be submitted for the following types of expedited and followup reports:

- Serious and unexpected SADR reports that contain a full data set,
- Information sufficient to consider product administration changes,