

§ 314.80(c)(2)(iii) will submit these expedited reports; and approximately 12 applicants under proposed § 600.80(c)(2)(iii) will submit these expedited reports. Based on the agency's familiarity with the content of expedited reports for serious and unexpected SADRs, FDA estimates that it will take an average of 24 hours for manufacturers and applicants to prepare and submit an expedited report for an unexpected SADR with an unknown outcome to FDA. Preparation of expedited reports for unexpected SADRs with an unknown outcome would include gathering information (proposed §§ 310.305(b) and (c)(1), 314.80(b) and (c)(1), and 600.80(b) and (c)(1)), providing attachments, if applicable (proposed §§ 310.305(c)(2)(ix) and (c)(2)(x), 314.80(c)(2)(ix), and 600.80(c)(2)(ix)), and formatting information (proposed §§ 310.305(c)(2)(xii), (d), and (e), 314.80(c)(2)(xi), (c)(4), and (e), and 600.80(c)(2)(xi), (c)(4), and (e)).

Proposed §§ 310.305(c)(2)(iv), 314.80(c)(2)(iv), and 600.80(c)(2)(iv) would require manufacturers and applicants to submit to FDA each SADR, received or otherwise obtained, whether foreign or domestic, that is the subject of an always expedited report. Certain medically significant SADRs (*e.g.*, ventricular fibrillation, liver necrosis, confirmed or suspected transmission of an infectious agent by a marketed drug or biological product) which may jeopardize the patient or subject and/or require medical or surgical intervention to treat the patient or subject would be subject to an always expedited report. These SADRs would be submitted to FDA whether unexpected or expected and whether or not the SADR leads to a serious outcome. Always expedited reports would be submitted to the agency within 15 calendar days after initial receipt by the manufacturer or applicant of the minimum data set for the report. Always expedited reports are a new type of safety report. Based on data concerning the number of safety reports currently received by the agency for the SADRs specified under proposed §§ 310.305(c)(2)(iv), 314.80(c)(2)(iv), and 600.80(c)(2)(iv), FDA estimates that approximately 50 always expedited reports will be submitted annually under proposed § 310.305(c)(2)(iv); approximately 1,500 reports will be submitted annually under proposed § 314.80(c)(2)(iv); and approximately 100 reports will be submitted annually under proposed § 600.80(c)(2)(iv). FDA estimates that approximately 10 manufacturers under proposed § 310.305(c)(2)(iv) will submit these

expedited reports; approximately 100 applicants under proposed § 314.80(c)(2)(iv) will submit these expedited reports; and approximately 10 applicants under proposed § 600.80(c)(2)(iv) will submit these expedited reports. Based on the agency's familiarity with the content of expedited reports for serious and unexpected SADRs, FDA estimates that it will take an average of 16 hours for manufacturers and applicants to prepare and submit an always expedited report to the agency. Preparation of always expedited reports would include gathering information (proposed §§ 310.305(b) and (c)(1), 314.80(b) and (c)(1), and 600.80(b) and (c)(1)), providing attachments, if applicable (proposed §§ 310.305(c)(2)(ix) and (c)(2)(x), 314.80(c)(2)(ix), and 600.80(c)(2)(ix)), and formatting information (proposed §§ 310.305(c)(2)(xii), (d), and (e), 314.80(c)(2)(xi), (c)(4), and (e), and 600.80(c)(2)(xi), (c)(4), and (e)).

Proposed §§ 310.305(c)(2)(v), 314.80(c)(2)(v), and 600.80(c)(2)(v) would require manufacturers and applicants to submit all domestic reports of medication errors, whether actual or potential. Expedited reports of medication errors are a new type of safety report. Based on data concerning the number of domestic reports of medication errors voluntarily submitted to the agency, FDA estimates that approximately 1,000 reports of medication errors will be submitted annually under proposed § 310.305(c)(2)(v); approximately 100,000 reports will be submitted annually under proposed § 314.80(c)(2)(v); and approximately 10,000 reports will be submitted annually under proposed § 600.80(c)(2)(v). FDA estimates that approximately 10 manufacturers under proposed § 310.305(c)(2)(v) will submit these expedited reports; approximately 150 applicants under proposed § 314.80(c)(2)(v) will submit these expedited reports; and approximately 30 applicants under proposed § 600.80(c)(2)(v) will submit these expedited reports. Based on the agency's familiarity with the content of expedited reports for serious and unexpected SADRs, FDA estimates that it will take an average of 16 hours for manufacturers and applicants to prepare and submit an expedited report of a medication error to the agency. Preparation of medication error reports would include gathering information (proposed §§ 310.305(b) and (c)(1), 314.80(b) and (c)(1), and 600.80(b) and (c)(1)), providing attachments, if

applicable (proposed §§ 310.305(c)(2)(ix) and (c)(2)(x), 314.80(c)(2)(ix), and 600.80(c)(2)(ix)), and formatting information (proposed §§ 310.305(c)(2)(xii), (d), and (e), 314.80(c)(2)(xi), (c)(4), and (e), and 600.80(c)(2)(xi), (c)(4), and (e)).

Proposed §§ 310.305(c)(2)(vi), 314.80(c)(2)(vi), and 600.80(c)(2)(vi) would require manufacturers and applicants to submit a 30-day followup report to FDA for any expedited report under proposed §§ 310.305(c)(2)(i), (c)(2)(iv), (c)(2)(v), 314.80(c)(2)(i), (c)(2)(iv), (c)(2)(v), 600.80(c)(2)(i), (c)(2)(iv), and (c)(2)(v) that does not contain a full data set. These 30-day followup reports would be submitted within 30 calendar days after submission of the expedited report. Thirty-day followup reports are a new type of safety report. Based on data concerning the number of followup reports received by the agency, FDA estimates that approximately 340 30-day followup reports will be submitted annually under proposed § 310.305(c)(2)(vi); approximately 43,000 30-day followup reports will be submitted annually under proposed § 314.80(c)(2)(vi); and approximately 3,000 30-day followup reports will be submitted annually under proposed § 600.80(c)(2)(vi). FDA estimates that approximately 7 manufacturers under proposed § 310.305(c)(2)(vi) will submit 30-day follow up reports; approximately 140 applicants under proposed § 314.80(c)(2)(vi) will submit 30-day follow up reports; and approximately 69 applicants under proposed § 600.80(c)(2)(vi) will submit 30-day followup reports. Based on the agency's familiarity with the content of followup reports for serious and unexpected SADRs, FDA estimates that it will take an average of 8 hours for manufacturers and applicants to prepare and submit a 30-day follow up report to the agency. Preparation of 30-day follow up reports would include gathering information (proposed §§ 310.305(b) and (c)(1), 314.80(b) and (c)(1), and 600.80(b) and (c)(1)), providing attachments, if applicable (proposed §§ 310.305(c)(2)(ix) and (c)(2)(x), 314.80(c)(2)(ix), and 600.80(c)(2)(ix)), and formatting information (proposed §§ 310.305(c)(2)(xii), (d), and (e), 314.80(c)(2)(xi), (c)(4), and (e), and 600.80(c)(2)(xi), (c)(4), and (e)).

Proposed §§ 310.305(c)(2)(vii), 314.80(c)(2)(vii), and 600.80(c)(2)(vii) would require manufacturers and applicants to submit a 15-day followup report to FDA concerning any new information, received or otherwise obtained, after any initial expedited report or any followup report, except for