

submission of safety records, FDA estimates that approximately 2 requests for submission of records will be fulfilled annually under proposed § 310.305(f)(1), approximately 15 requests for submission of records will be fulfilled annually under proposed § 314.80(f), and approximately 4 requests for submission of records will be fulfilled annually under proposed § 600.80(f). FDA estimates that approximately 2 manufacturers and contractors under proposed § 310.305 will submit these records, approximately 15 applicants and contractors under proposed § 314.80 will submit these records, and approximately 4 applicants, contractors and shared manufacturers under proposed § 600.80 will submit these records. Based on the volume of safety information voluntarily submitted to FDA in response to an agency request for such information, FDA estimates that it will take an average of 8 hours for manufacturers, applicants, contractors, and shared manufacturers to fulfill each request for submission of records to the agency.

Proposed § 314.81(b)(2) would require applicants of marketed drug products subject to an NDA to submit an annual report to FDA within 60 days of the anniversary date of U.S. approval of the application. This report would contain summary information; distribution data; chemistry, manufacturing, and controls changes; clinical data; and a status report of any postmarketing studies performed by, or on behalf of, the applicant. Based on data concerning the number of approved NDA annual reports received by the agency, FDA estimates that approximately 2,363 reports will be submitted under proposed § 314.81(b)(2). FDA estimates that approximately 286 applicants will submit these reports. Based on the agency's familiarity with the content of approved NDA annual reports, FDA estimates that it will take an average of 35.5 hours for applicants to prepare and submit one of these annual reports to FDA.

Proposed § 601.28 would require applicants of licensed biological products to submit an annual report of postmarketing pediatric studies to FDA within 60 days of the anniversary date of approval of the application. This report would contain summary information, clinical data in the pediatric population, and a status report of any postmarketing studies in the pediatric population. Based on data concerning the number of approved BLA annual reports received by the agency, FDA estimates that approximately 69 reports will be

submitted under proposed § 601.28. FDA estimates that approximately 69 applicants will submit these reports. Based on the agency's familiarity with the content of approved BLA annual reports, FDA estimates that it will take an average of 25 hours for applicants to prepare and submit an annual report to the agency.

#### *VI.D. Recordkeeping*

Proposed §§ 310.305(c)(2)(xi)(B), 314.80(c)(2)(x)(B), and 600.80(c)(2)(x)(B) would require that contracts between manufacturers and contractors (proposed § 310.305(c)(2)(xi)(B)) and applicants and contractors (proposed §§ 314.80(c)(2)(x)(B) and 600.80(c)(2)(x)(B)) specify the safety reporting responsibilities of the contractor. For purposes of this section, a record represents a contract. Based on information contained in individual case safety reports submitted to the agency in the past (*i.e.*, report source), FDA estimates that approximately 4 records will be maintained annually under proposed § 310.305(c)(2)(xi)(B), approximately 480 records will be maintained annually under proposed § 314.80(c)(2)(x)(B), and approximately 2 records will be maintained annually under proposed § 600.80(c)(2)(x)(B). FDA estimates that approximately 2 manufacturers under proposed § 310.305 will maintain these records, approximately 160 applicants under proposed § 314.80 will maintain these records, and approximately 2 applicants under proposed § 600.80 will maintain these records. Based on the agency's familiarity with recordkeeping processes, FDA estimates that it will take an average of 1 hour for manufacturers and applicants to maintain each record annually under proposed §§ 310.305(c)(2)(xi)(B), 314.80(c)(2)(x)(B), and 600.80(c)(2)(x)(B).

Proposed §§ 310.305(f), 314.80(f), and 600.80(f) would require manufacturers, applicants, contractors, and shared manufacturers to maintain for a period of 10 years records of all safety information, received or otherwise obtained, including raw data; any correspondence relating to the safety information; and any reports of SADR or medication errors not submitted to FDA or only provided to FDA in a summary tabulation. These persons would also be required to retain for a period of 10 years any records required to be maintained under proposed § 310.305 (§ 310.305(c)(1)(ii), (c)(1)(iii)(A), (c)(2)(ii), (c)(2)(viii)(A), and (c)(2)(xi)(C)), proposed § 314.80 (§ 314.80(c)(1)(ii), (c)(1)(iii)(A), (c)(2)(ii), (c)(2)(viii)(A), and (c)(2)(x)(C)), and

proposed § 600.80 (§ 600.80(c)(1)(ii), (c)(1)(iii)(A), (c)(2)(ii), (c)(2)(viii)(A), and (c)(2)(x)(C)). For the purposes of this section, a record includes any and all documentation regarding an individual SADR or medication error. Based on data concerning the number of SADRs currently reported to the agency, FDA estimates that approximately 500 records will be maintained annually under proposed § 310.305(f), approximately 220,000 records will be maintained annually under proposed § 314.80(f), and approximately 20,000 records will be maintained annually under proposed § 600.80(f). FDA estimates that approximately 25 manufacturers and contractors under proposed § 310.305 will maintain these records, approximately 700 applicants and contractors under proposed § 314.80 will maintain these records, and approximately 69 applicants, contractors, and shared manufacturers under proposed § 600.80 will maintain these records. Based on the agency's familiarity with recordkeeping processes, FDA estimates that it will take an average of 5 hours for manufacturers, applicants, contractors, and shared manufacturers to maintain each record annually under proposed §§ 310.305, 314.80, and 600.80.

Proposed §§ 310.305(g), 314.80(g), and 600.80(g) would require manufacturers, applicants, contractors, and shared manufacturers to maintain written procedures for the surveillance, receipt, evaluation, and reporting of safety information to FDA. Based on the number of persons subject to the postmarketing safety reporting regulations, FDA estimates that approximately 25 records will be maintained annually under proposed § 310.305(g), approximately 700 records will be maintained annually under proposed § 314.80(g), and approximately 69 records will be maintained annually under proposed § 600.80(g). FDA estimates that approximately 25 manufacturers and contractors under proposed § 310.305 will maintain these records, approximately 700 applicants and contractors under proposed § 314.80 will maintain these records, and approximately 69 applicants, contractors, and shared manufacturers under proposed § 600.80 will maintain these records. Based on the agency's familiarity with recordkeeping processes, FDA estimates that it will take an average of 1 hour for manufacturers, applicants, contractors, and shared manufacturers to maintain a record of the written procedures