

reporting period. The timing for these report submissions would be at 5, 7.5, 10, 12.5, and 15 years after U.S. approval of the product and then every 5 years thereafter. Applicants would have the option to file using the PSUR and IPSR formats.

The additional times required to complete the proposed changes to postmarketing periodic safety report submissions are shown in table 15. The agency estimates that the new burdens would be 16 hours for TPSRs, 40 hours

for PSURs, and 30 hours for IPSRs. These times represent estimates of the average time per report, recognizing that preparation times for each postmarketing periodic safety reports may take as little as a day for products with few or no SADRs or as much as several months for other products that are more complex or associated with many SADRs. Based on reports received by the agency, a few products account for the majority of the reports of SADRs. For example, 1998 AERS data showed

that approximately 75 percent of the postmarketing periodic safety reports for drug products included 10 or fewer individual case safety reports, accounting for only about 5 percent of all of those reports submitted with postmarketing periodic safety reports. The other 25 percent of postmarketing periodic safety reports included the remaining 95 percent of individual case safety reports submitted in 1998.

TABLE 15.—ESTIMATED NEW BURDEN FOR PERIODIC SAFETY REPORTS AND OTHER REPORTS

Type of report	New or revised	New burden (hours)			
		Health professional	Regulatory affairs	Clerical	Total
<i>Periodic:</i>					
TPSR—application approved before 1/1/95	Revised	3	9	4	16
PSUR—application approved on or after 1/1/95	New	8	24	8	40
IPSR—application approved on or after 1/1/95	New	6	18	6	30
<i>Other:</i>					
Reports of nonserious SADRs and certain medication errors to manufacturer or applicant.	New	0	1	0	1
Submit safety records to FDA upon request	New	0	4	4	8
Annual reports	Revised	¹ (3)	(7.5)	(3)	(14)

¹ Values in parentheses represent an estimate of the decrease in burden.

V.D.1.b.vii. *Other reports.* Currently, persons submitting postmarketing safety reports may elect to submit reports of serious adverse drug experiences to the manufacturer or applicant rather than submitting serious unexpected adverse drug experiences directly to FDA. The proposed rule would require submission of all safety reports (*i.e.*, serious and nonserious SADRs and medication errors) to the manufacturer or applicant within 5 calendar days of initial receipt of the information. Contractors may need to allocate up to 1 additional hour to prepare and submit each report of a nonserious SADR or medication error that does not result in an SADR (see table 15).

Persons maintaining records of SADRs may be asked to submit any or all records to FDA within 5 calendar

days. The agency estimates that 21 such requests for SADR records would be made in a given year. This new reporting requirement may take regulatory affairs and clerical personnel up to 4 hours each to fulfill each request (see table 15).

FDA will no longer require that applicants subject to an NDA or BLA submit certain safety related information with annual reports. This reduction in reporting requirements will decrease the burden on these applicants. To prepare and submit each annual report, applicants may save an estimated 13.5 hours annually (see table 15).

V.D.1.c. *Annual cost of the reporting and recordkeeping provisions.* Hourly compensation estimates for personnel implicated in the proposed changes to

safety reports are shown in table 16. The additional cost of the proposed changes for each type of affected report and the total annual cost of the proposed rule are summarized in table 17. However, because the annual costs depend on the actual number and type of reports submitted to FDA, these costs are uncertain and may fluctuate from year to year. For example, if there are 50 percent fewer reports than estimated, annual costs would be approximately \$52.2 million instead of \$106.6 million. If the number of reports submitted is 50 percent more than shown in table 17, the annual costs would be about \$159.9 million. The agency seeks comments on the reasonableness of its estimates of number of reports, burden hours, and costs.

TABLE 16.—HOURLY COMPENSATION

Health Practitioner ¹	Regulatory Affairs ^{2,3}	Clerical ²
\$67.31	\$36.92	\$17.39

¹ Hourly compensation derived from the annual salary range for clinical research physicians in the pharmaceutical industry from <http://careers.yahoo.com>. Hourly compensation includes benefits equal to 40 percent of hourly wage.

² U.S. Department of Labor, BLS, "Employer Costs for Employee Compensation, Table 12," March 1999.

³ Includes biostatisticians.