

TABLE 21.—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>—Continued

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Hours per response	Total hours
600.80(c)(3)(i), (c)(3)(iii), and (c)(3)(iv) .....	3	1	3	30	90
600.80(c)(3)(v) .....	69	6.9	480	120	57,600
600.80(f) .....	4	1	4	8	32
601.28 .....	69	1	69	25	1,725
606.170(b) .....	3,062	2.3	7,000	16	112,000
606.170(c) .....	75	1	75	20	1,500
Total .....	23,283	2,149.7	424,794	896.5	4,541,113

<sup>1</sup> The estimates provided in this table are not only attributed to the new proposed requirements in this rulemaking but also include burdens associated with our current safety reporting requirements. There are no capital costs or operating and maintenance costs associated with this collection of information.

<sup>2</sup> The paragraphs of § 310.305 cited in the table include burdens associated with gathering information under § 310.305(b) and (c)(1), providing attachments, if applicable, under § 310.305(c)(2)(ix) and (c)(2)(x), and formatting information under § 310.305(c)(2)(xii), (d), and (e).

<sup>3</sup> The paragraphs of § 312.32 cited in the table include burdens associated with gathering information under § 312.32(b) and formatting information under § 312.32(c)(1)(iii).

<sup>4</sup> The paragraphs of § 314.80 cited in the table include burdens associated with gathering information under § 314.80(b) and (c)(1), providing attachments, if applicable, under § 314.80(c)(2)(ix) and (c)(3), and formatting information under § 314.80(c)(2)(xi), (c)(4), and (e).

<sup>5</sup> The paragraphs of § 600.80 cited in the table include burdens associated with gathering information under § 600.80(b) and (c)(1), providing attachments, if applicable, under § 600.80(c)(2)(ix) and (c)(3), and formatting information under § 600.80(c)(2)(xi), (c)(4), and (e).

TABLE 22.—ESTIMATED ANNUAL RECORDKEEPING BURDEN <sup>1</sup>

21 CFR section	Number of recordkeepers	Annual frequency of recordkeeping	Total annual records	Hours per record	Total hours
310.305(c)(2)(xi)(B) .....	2	2	4	1	4
310.305(f) <sup>2</sup> .....	25	20	500	5	2,500
310.305(g) .....	25	1	25	1	25
312.32(c)—human drugs .....	50	4	200	1	200
312.32(c)—human biological products .....	60	4	240	1	240
314.80(c)(2)(x)(B) .....	160	3	480	1	480
314.80(f) <sup>3</sup> .....	700	314.3	220,000	5	1,100,000
314.80(g) .....	700	1	700	1	700
600.80(c)(2)(x)(B) .....	2	1	2	1	2
600.80(f) <sup>4</sup> .....	69	289.8	20,000	5	100,000
600.80(g) .....	69	1	69	1	69
606.170(a) .....	376	12	4,512	12	54,144
Total .....	2,238	653.1	246,732	35	1,258,364

<sup>1</sup> The estimates provided in this table are not only attributed to the new proposed requirements in this rulemaking but also include burdens associated with our current safety reporting requirements. There are no capital costs or operating costs associated with this collection of information. There are maintenance costs of \$2,025 annually per recordkeeper (\$2,000 annually per recordkeeper for existing recordkeeping requirements (see 67 FR 47821) and \$25 annually per recordkeeper for new proposed requirements in this rulemaking).

<sup>2</sup> Includes records required to be maintained under § 310.305(c)(1)(ii), (c)(1)(iii)(A), (c)(2)(ii), (c)(2)(viii)(A), and (c)(2)(xi)(C).

<sup>3</sup> Includes records required to be maintained under § 314.80(c)(1)(ii), (c)(1)(iii)(A), (c)(2)(ii), (c)(2)(viii)(A), and (c)(2)(x)(C).

<sup>4</sup> Includes records required to be maintained under § 600.80(c)(1)(ii), (c)(1)(iii)(A), (c)(2)(ii), (c)(2)(viii)(A), and (c)(2)(x)(C).

## VII. Executive Order 13132: Federalism

Executive Order 13132 requires Federal agencies to carefully examine regulatory actions to determine if they would have a significant impact on federalism. Using the criteria and principles set forth in the Executive order, the agency has considered the impact of this proposed rule on the States, on their relationship with the Federal Government, and on the distribution of power and responsibilities among the various levels of government.

FDA is publishing this proposed rule to revise its regulations governing the format, content, and submission of safety reports to the agency for human drugs and biological products. The proposal would revise current

regulations to implement definitions and reporting formats and standards recommended by ICH and CIOMS. The proposal would codify the agency's expectations for timely acquisition, evaluation, and submission of relevant safety information for marketed drugs and biological products. The proposal would require that postmarketing individual case safety reports of unexpected SADRs that cannot be classified as either serious or nonserious be submitted to the agency in an expedited manner. The proposal would also require that certain medically significant SADRs always be submitted to FDA in an expedited manner whether the SADR is unexpected or expected. The proposal would also require that all domestic reports of medication errors,

whether actual or potential, be submitted to FDA in an expedited manner. The proposal would clarify certain safety reporting requirements and make other minor revisions. The proposal would also amend the agency's postmarketing annual reports regulations for applicants of human drugs and licensed biological products to revise the content for these reports. The proposal would also amend the agency's bioavailability and bioequivalence study regulations for sponsors of human drugs to require expedited safety reports for certain studies which are exempt from submission of an IND. Because enforcement of these safety reporting requirements would be a Federal responsibility, there would be little, if