

annually under proposed §§ 310.305(g), 314.80(g), and 600.80(g).

Proposed § 312.32(c) would require sponsors to maintain records for reports of SADR that do not contain a minimum data set. This would include any information received or otherwise obtained for the SADR along with a record of their efforts to obtain a minimum data set for the report. For the purposes of this section, a record includes any and all documentation regarding an individual SADR. Maintaining records of SADRs that do not contain a minimum data set represents a new recordkeeping requirement. Based on information contained in IND safety reports, FDA estimates that approximately 200 records will be maintained annually under proposed § 312.32(c) for human drugs; approximately 240 records will be maintained annually under proposed § 312.32(c) for human biological products. FDA estimates that

approximately 50 sponsors will maintain these records for human drugs and approximately 60 sponsors will maintain these records for human biological products. Based on the agency's familiarity with recordkeeping processes, FDA estimates that it will take an average of 1 hour for sponsors to maintain each record annually under proposed § 312.32(c).

Proposed § 606.170(a) would require blood collection and transfusing facilities to maintain records for complaints of SARs regarding each unit of blood or blood product. These facilities must prepare a written report of the investigation of SARs, including followup and conclusions. Based on data for records currently maintained by blood collection and transfusing facilities, FDA estimates that approximately 4,512 records will be maintained annually under proposed § 606.170(a). FDA estimates that approximately 376 facilities will

maintain these records. Based on the agency's familiarity with recordkeeping processes, FDA estimates that it will take an average of 12 hours for facilities to maintain each record annually under proposed § 606.170(a).

Description of Respondents: Business or other for-profit organizations.

In compliance with section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)), the agency has submitted a copy of this proposed rule to OMB for its review and approval of these information collections. Interested persons are requested to send comments regarding this information collection, including suggestions for reducing this burden, to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, OMB, Attn: Stuart Shapiro, Desk Officer for FDA, FAX: 202-395-6974. Submit written comments on the information collection by April 14, 2003.

TABLE 21.—ESTIMATED ANNUAL REPORTING BURDEN¹

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Hours per response	Total hours
310.305(c)(2)(i) ²	14	25	350	16	5,600
310.305(c)(2)(ii)	5	1	5	8	40
310.305(c)(2)(iii)	10	4.6	46	24	1,104
310.305(c)(2)(iv)	10	5	50	16	800
310.305(c)(2)(v)	10	100	1,000	16	16,000
310.305(c)(2)(vi)	7	48.6	340	8	2,720
310.305(b)(2), (c)(2)(vii), and (c)(2)(viii)(A)	10	5.5	55	4	220
310.305(c)(2)(xi)	5	2	10	2	20
310.305(f)(1)	2	1	2	8	16
312.32(c)(1)(i) ³ —human drugs	457	10.6	4,860	16	77,760
312.32(c)(1)(ii)—human drugs	100	3	300	8	2,400
312.32(c)(2)—human drugs	135	3.6	490	4	1,960
312.32(c)(1)(i)—human biological products	602	4.9	2,980	16	47,680
312.32(c)(1)(ii)—human biological products	100	3	300	8	2,400
312.32(c)(2)—human biological products	180	1.6	290	4	1,160
312.64(b)—human drugs	10,000	10	100,000	2	200,000
312.64(b)—human biological products	6,000	10	60,000	2	120,000
314.80(c)(2)(i) ⁴	282	177.3	50,000	16	800,000
314.80(c)(2)(ii)	50	6	300	8	2,400
314.80(c)(2)(iii)	109	8.4	912	24	21,888
314.80(c)(2)(iv)	100	15	1,500	16	24,000
314.80(c)(2)(v)	150	666.7	100,000	16	1,600,000
314.80(c)(2)(vi)	140	307.1	43,000	8	344,000
314.80(b)(2), (c)(2)(vii), and (c)(2)(viii)(A)	184	54.3	10,000	4	40,000
314.80(c)(2)(x)	100	113.7	11,370	2	22,740
314.80(c)(3)(i)	80	17.5	1,400	20	28,000
314.80(c)(3)(i), (c)(3)(ii), and (c)(3)(iv)	200	12.5	2,500	40	100,000
314.80(c)(3)(i), (c)(3)(iii), and (c)(3)(iv)	40	8.7	350	30	10,500
314.80(c)(3)(v)	285	16.6	4,726	120	567,120
314.80(f)	15	1	15	8	120
314.81(b)(2)	286	8.3	2,363	35.5	83,886
320.31(d)(3)	10	20	200	14	2,800
600.80(c)(2)(i) ⁵	69	43.5	3,000	16	48,000
600.80(c)(2)(ii)	4	1	4	8	32
600.80(c)(2)(iii)	12	2.1	25	24	600
600.80(c)(2)(iv)	10	10	100	16	1,600
600.80(c)(2)(v)	30	333.3	10,000	16	160,000
600.80(c)(2)(vi)	69	43.5	3,000	8	24,000
600.80(b)(2), (c)(2)(vii), and (c)(2)(viii)(A)	69	14.5	1,000	4	4,000
600.80(c)(2)(x)	20	12.5	250	2	500
600.80(c)(3)(i)	20	1.8	35	20	700
600.80(c)(3)(i), (c)(3)(ii), and (c)(3)(iv)	20	1.8	35	40	1,400