

812.36(f) identifies the reports required to allow FDA to monitor the size and scope of the treatment IDE, to assess the sponsor's due diligence in obtaining marketing clearance of the device, and to ensure the integrity of the controlled clinical trials.

Section 812.140 lists the recordkeeping requirements for investigators and sponsors. FDA requires this information for tracking and oversight purposes. Investigators are required to maintain records, including correspondence and reports concerning the study; records of receipt, use or disposition of devices; records of

each subject's case history and exposure to the device; informed consent documentation; study protocol and documentation of any deviation from the protocol. Sponsors are required to maintain records, including correspondence and reports concerning the study; records of shipment and disposition; signed investigator agreements; adverse device effects information; and, for a nonsignificant risk device study, an explanation of the nonsignificant risk determination, records on device name and intended use, study objectives, investigator

information, investigational review board (IRB) information, and statement on the extent that good manufacturing practices will be followed.

The most likely respondents to this information collection will primarily be medical device manufacturers, investigators, hospitals, health maintenance organizations, and businesses.

In the **Federal Register** of March 12, 2003 (68 FR 11868), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
812.10	1	1	1	1	1
812.20, 812.25, and 812.27	600	0.5	300	80	24,000
812.35 and 812.150 (significant)	600	7	4,200	6	25,200
812.150 (non-significant)	600	0.017	10	6	60
812.36(c)	6	1	6	120	720
812.36(f)	6	2	12	20	240
Total					50,221

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN¹

21 CFR Section	No. of Recordkeepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Record	Total Hours
812.140 Original	600	0.5	300	10	3,000
Supplemental	600	7	4,200	1	4,200
Nonsignificant	600	1	600	6	3,600
Total					10,800

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

II. Reporting

Section 812.10 estimates are based on the fact that FDA has received very few, if any, waiver requests in the past, and estimates that very few will be submitted in the future. Therefore, FDA estimates a minimal burden to account for waiver requests.

Sections 812.20, 812.25, and 812.27 estimates are based on the average of IDEs submitted from fiscal years 1995

through 2002. FDA estimates the annual reporting burden for one IDE original application to be approximately 80 hours and the annual reporting burden for one IDE supplement to be approximately 6 hours.

Sections 812.35 and 812.150 estimates are based on the average of IDE supplements submitted from fiscal years 1995 through 2002 for significant risk device studies. FDA estimates the annual reporting burden for one IDE

supplement to be approximately 6 hours.

The reporting burden for nonsignificant risk device studies (§ 812.150) is negligible. Nonsignificant risk device studies are not reported to FDA unless a problem is reported such as, an unanticipated adverse device reaction, failure to obtain informed consent, withdrawal of IRB approval, or a recall of a device. In the past, an