TABLE 4.—ESTIMATED ANNUAL BURDEN FOR REPORTING—Continued

CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Hours per response	Total hours
803.30(a)	700	1.0	700	3.0	2,100
803.30(b)	20,000	1.5	30,000	3.0	90,000
803.33	2,000	1.0	2,000	1.0	2,000
803.50	1,250	40.0	50,000	0.5	25,000
803.53	100	1.0	100	0.5	50
803.55	1,000	20.0	20,000	[1] 1.1	22,000
803.56	500	20.0	10,000	1.0	10,000
803.57	12,000	1.0	12,000	1.0	12,000
803.58	5,000	1.0	5,000	1.0	5,000
Total					168,450

[1] Although an initial submission will take an estimated 2 hours to complete, the annual update will take only .5 hours. The average hours per response is therefore 1.1, as reflected here.

TABLE 5.—ESTIMATED ANNUAL BURDEN FOR RECORDKEEPING

CFR section	Number of record-keepers	Hours per record-keeper	Total hours
803.18(c)	36,639	0.25	9,160
803.18(e)	625	16.00	10,000
Total			19,160

Although the November 26, 1991, tentative final rule provided a 60-day comment period (extended to 90 days in the January 24, 1992, Federal Register, 57 FR 2861), and this final rule is based on the comments received, FDA Form 3419 (semiannual report), FDA Form 3417 (baseline report), and FDA Form 3381 (annual certification) have not been previously available to OMB or the public for review. Therefore, as required by section 3507(d) of the Paperwork Reduction Act of 1995, FDA has submitted a copy of this final rule to OMB for its review of these information collection requirements.

In addition, the agency solicits public comment on the information collection requirements in order to: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) enhance the quality, utility, and clarity of the information to be collected; and (4) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Individuals and organizations may submit comments on the information collection requirements by January 10, 1996, and should direct them to FDA's Dockets Management Branch (address above) and to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., rm. 10235, 725 17th St. NW., Washington, DC 20503, Attention: Desk Officer for FDA.

Persons are not required to respond to a collection of information unless it displays a currently valid OMB control number. This final rule contains information collection requirements which have been approved under OMB no. 0910–0059 and which expires on March 31, 1996. FDA will publish a notice in the Federal Register prior to the effective date of this final rule of OMB's decision to approve, modify or disapprove the information collection requirements.

List of Subjects

21 CFR Part 803

Imports, Medical devices, Reporting and recordkeeping requirements.

21 CFR Part 807

Confidential business information, Medical devices, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under the authority delegated to the Commissioner of Food and Drugs, chapter I of title 21 of the Code of Federal Regulations is amended as follows:

1. Part 803 is revised to read as follows:

PART 803—MEDICAL DEVICE REPORTING

Subpart A—General Provisions

Sec.

Subpart B—Generally Applicable Requirements for Individual Adverse Event Reports