

distributors of medical devices. In addition, section 303 of the Medical Device User Fee and Modernization Act of 2002 directs FDA to modify the MedWatch mandatory and voluntary forms to facilitate the reporting of information by user facilities or distributors as appropriate relating to

reprocessed single-use devices, including the name of the reprocessor and whether the device has been reused.

*C. Other Products Used in Medical Therapy*

There are no mandatory requirements for the reporting of adverse events or

product problems with products such as dietary supplements.

FDA estimates the burden for completing the forms for this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN

FDA Center/(21 CFR Section)	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
<b>CBER/CDER</b>					
Form 3500	20,074	1	20,074	0.5	10,037
Form 3500A (§§ 310.305, 314.80, 314.98, and 600.80)	600	463.86	278,315	1.0	278,315
<b>CDRH</b>					
Form 3500	3,252	1	3,252	0.5	1,626
Form 3500A (part 803)	1,935	33	63,623	1.0	63,623
§ 803.10	2,845	2.4	6,828	.17	1,160
<b>CFSAN</b>					
Form 3500	895	1	895	0.5	448
Form 3500A (no mandatory requirements)	0	0	0	1.0	0
<b>Total Hours</b>					<b>355,209</b>
Form 3500					13,271
Form 3500A					343,098

(NOTE: CBER = Center for Biologics Evaluation and Research; CDER = Center for Drug Evaluation and Research; CDRH = Center for Devices and Radiological Health; and CFSAN = Center for Food Safety and Applied Nutrition. FDA Form 3500 is for voluntary reporting; FDA Form 3500A is for mandatory reporting.)

The figures shown in table 1 of this document are based on actual calendar

year 2002 reports and respondents for each center and type of report.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN<sup>1</sup>

FDA Center/21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
<b>CDRH</b>					
803.10	2,845	2.4	6,828	.17	1,160
<b>Total</b>					<b>1,160</b>

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

In the **Federal Register** of February 10, 2003 (68 FR 6752), FDA published a 60-day notice requesting public comment on the information collection provisions. Two comments from organizations (Health Industry Manufacturers Association and Baxter Healthcare Corp.) were submitted. In general, the comments supported the reinstatement of the 3500A form with little or no modification since most

manufacturers had made investments in systems that produce computer facsimiles of the form. Both organizations also questioned the need for a medical device “Baseline Report,” saying that most of the information is already provided to FDA on either the 3500A form or through the Medical Device registration and listing process.

FDA recognized the impact that a major modification of the 3500A form

would have on computerized systems in place across the pharmaceutical and medical device industry. In addition, the agency agreed that there is redundancy of certain data elements among the 3500A, Baseline Report and the Medical Device Registration and Listing Process. However, the agency also felt that certain elements found on the baseline form and not duplicated elsewhere were essential. At that time,