TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
803.19	25	1	25	1	75
803.30	1,000	3	3,000	1	3,000
803.33 FDA Form 3419	1,000	1	1,000	1	1,000
803.40	50	10	500	1	500
803.50	1,500	34	51,000	1	51,000
803.55 FDA Form 3417	700	5	3,500	1	3,500
Total					59,075

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

TABLE 2.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
803.17	3,200	1	3,200	3.3	10,560
803.18[2]	39,000	1	39,000	1.5	58,500
Total					69,060

[1] There are no capitol costs or operating and maintenance costs associated with this collection of information.
[2] Include an estimated 35,000 medical device distributors. Although they do not submit medical device reports, they must maintain records of complaints.

The agency believes that the majority of manufacturers, user facilities, and importers have already established written procedures to document complaints and information to meet the medical device report (MDR) requirements as part of their internal quality control system.

Part 803 requires user facilities to report incidents where a medical device caused or contributed to a death or serious injury to the device manufacturer and to FDA (in case of death). Manufacturers of medical devices are required to report to FDA when they become aware of information indicating that one of their devices may have caused or contributed to death or serious injury or has malfunctioned in such a way that should the malfunction recur, it would be likely to cause or contribute to death or serious injury. Device importers report deaths and serious injuries to the manufacturers and FDA. Importers report malfunctions only to the manufacturers, unless they are unknown. If the manufacturer is unknown, the importer sends the reports to FDA.

The agency has estimated that on average, 1,800 entities annually would be required to establish new procedures or revise existing procedures in order to comply with MDR provisions. For those entities, a one-time burden of 10 hours is estimated for establishing written MDR procedures. The remaining manufacturers, user facilities, and importers which are not required to revise their written procedures to comply with this provision are excluded from the burden because the recordkeeping activities needed to comply with this provision are considered ''usual and customary'' under 5 CFR 1320.3(b)(2).

Dated: January 2, 2003.

Margaret M. Dotzel,

Assistant Commissioner for Policy.

[FR Doc. 03–361 Filed 1–8–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02D–0509]

International Conference on Harmonisation; Draft Guidance on the M4 Common Technical Document—Quality: Questions and Answers/ Location Issues; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration is correcting a notice that appeared in the **Federal Register** of December 30, 2002 (67 FR 79639). The document announced the availability of a draft guidance entitled ''Common Technical Document—Quality: Questions and Answers/Location Issues.'' The document was published with an inadvertent error. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Joyce Strong, Office of Policy (HF–27), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7010.

SUPPLEMENTARY INFORMATION: In FR Doc. 02–32852, appearing on page 79639 in the **Federal Register** of Monday, December 30, 2002, the following correction is made:

1. On page 79639, in the first column, in the heading of the document, ''[Docket No. 02N–0509]'' is corrected to read ''[Docket No. 02D–0509]''.

Dated: January 3, 2003.

Margaret M. Dotzel,

Assistant Commissioner for Policy.

[FR Doc. 03–360 Filed 1–8–03; 8:45 am]

BILLING CODE 4160–01–S