

application. This time is consistent with the current recordkeeping requirements for other information related to marketing applications for human drugs, biologics, and medical devices.

Currently, sponsors of covered studies must maintain many records with regard to clinical investigators, including protocol agreements and investigator resumes or curriculum

vitae. FDA estimates that an average of 15 minutes will be required for each recordkeeper to add this record to clinical investigators' file.

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

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
54.6	1,000	1	1,000	.25	250

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

Dated: July 19, 2001.

**Margaret M. Dotzel,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 01N-0175]

#### Agency Information Collection Activities; Submission for OMB Review; Comment Request; Survey of Single-Use Medical Device Reuse and Reprocessing in Hospitals

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Submit written comments on the collection of information by August 24, 2001.

**ADDRESSES:** Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Wendy Taylor, Desk Officer for FDA.

**FOR FURTHER INFORMATION CONTACT:** Peggy Schlosburg, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223.

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

#### Survey of Single-Use Medical Device Reuse and Reprocessing in Hospitals

Section 1701(a)(4) of the Public Health Service Act (42 U.S.C. 300u(a)(4)) authorizes FDA to conduct research relating to health information. The "Survey of Single-Use Medical Device Reuse and Reprocessing in Hospitals" will provide information on the frequency, nature, and scope of reuse and reprocessing of single-use medical devices by U.S. hospitals. The survey will provide statistically reliable estimates of the number of U.S.

hospitals that are currently reusing and internally reprocessing single-use medical devices, whether they have registered with FDA, whether they are aware of the FDA educational materials on the reuse of single-use medical devices, and, if they are not currently internally reprocessing single-use devices, whether they have reused and reprocessed single-use medical devices in the past 3 years.

FDA will use these results to estimate the number of U.S. hospitals that reused and reprocessed single-use medical devices in the past, and those that currently reuse and internally reprocess single-use medical devices. This information will help FDA design its inspection plan, modify its education program, and evaluate the economic impact of current and future policies regarding single-use medical devices. The respondents to this collection of information will be U.S. hospitals.

In the **Federal Register** of April 30, 2001 (66 FR 21399), the agency requested comments on the proposed collection of information. No comments regarding paperwork were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN FOR TELEPHONE SURVEY<sup>1</sup>

No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
5,272	1	5,272	0.125	659

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

This is a one-time survey. The burden estimate for the telephone survey is based on a pretest of a preliminary survey instrument administered to nine hospitals. The number of respondents, total annual responses, and the total burden hours in this notice differs from the numbers in the notice published on April 30, 2001 (66 FR 21399). This is because the number of hospitals to be surveyed has changed based on more

current estimates of the number of hospitals in the United States.

Dated: July 18, 2001.

**Margaret M. Dotzel,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### Anesthetic and Life Support Drugs Advisory Committee; Notice of Meeting

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.