

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N-0399]

DMB

Display Date	01-24-02
Publication Date	01-25-02
Certifier	A. Corbin

**Agency Information Collection Activities; Submission for OMB Review; Comment Request; Rapid Response Surveys**

**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 [*insert date 30 days after date of publication in the Federal Register*].

**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: Stuart Shapiro, 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.

**Rapid Response Surveys (OMB Control No. 0910-0457)—Extension**

Under section 519 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360i), FDA is authorized to require manufacturers to report medical device related deaths, serious injuries,

and malfunctions, and user facilities to report device-related deaths directly to FDA and to manufacturers, and to report serious injuries to the manufacturer. Section 522 of the act (21 U.S.C. 360l) authorizes FDA to require manufacturers to conduct postmarket surveillance of medical devices. Section 705(b) of the act (21 U.S.C. 375(b)) authorizes FDA to collect and disseminate information regarding medical products or cosmetics in situations involving imminent danger to health, or gross deception of the consumer. Section 903(d)(2) of the act (21 U.S.C. 393(d)(2)) authorizes the Commissioner of Food and Drugs (the Commissioner) to implement general powers (including conducting research) to effectively carry out the mission of FDA. These sections of the act enable FDA to enhance consumer protection from risks associated with medical device usage that are not foreseen or apparent during the premarket notification and review process. FDA monitors medical product related postmarket adverse events via both the mandatory and voluntary MedWatch Reporting Systems using FDA Forms 3500 and 3500A (OMB Control No. 0910-0281).

FDA received a 1-year OMB approval on February 5, 2001, to implement Emergency Health Surveys (since that time, renamed "Rapid Response Surveys"), via a series of surveys, thus implementing section 705(b) of the act and the Commissioner's authority as specified in section 903(d)(2) of the act. To date, FDA has initiated one Rapid Response Survey (66 FR 49391, September 27, 2001), with two more in development. FDA is now seeking OMB clearance to continue collecting this information. Participation in these surveys has been, and will continue to be, voluntary. This request covers Rapid Response Surveys for general type medical facilities and specialized medical facilities (those known for cardiac surgery, obstetric/gynecological services, pediatric services, etc.), and health professionals, but more typically risk managers working in medical facilities.

FDA currently uses the information gathered from these surveys to quickly obtain vital information from the appropriate clinical sources so that FDA may take appropriate public health or regulatory action. FDA projects 10 rapid response surveys per year with a sample of between 50 and 200 respondents per survey.

In the **Federal Register** of September 27, 2001 (66 FR 49391), the agency requested comments on the proposed collection of information. No comments were received.

FDA originally estimated the burden of this collection to be 2 hours per survey. However, FDA is revising the estimated burden of this collection of information as follows:

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

No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
200	10 (maximum)	2,000	.5	1,000

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

These estimates are based on the maximum sample size per questionnaire that FDA could analyze in a timely manner. The annual frequency per response was determined by the maximum number of questionnaires that will be sent to any individual respondent. Some respondents may be contacted only one time per year, while another respondent may be contacted several times—depending on the medical device under evaluation. Based on the questions developed for the one survey that has been conducted, and for the two under development, it is estimated, given the

expected type of issues that will be addressed by the surveys, that at a maximum it will take 30 minutes for a respondent to gather the requested information and fill in the answers.

Dated: 1-17-02  
January 17, 2002.

  
\_\_\_\_\_  
Margaret M. Dotzel,  
Associate Commissioner for Policy.

[FR Doc. 02-????? Filed ??-??-02; 8:45 am]

BILLING CODE 4160-01-S

