

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N-0508]

DDM
Display Date 3-27-06
Publication Date 3-28-06
Author D. Hawkins

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Survey of Health Care Practitioners Regarding Their Preferences for Public Health Notifications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

---

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

**DATES:** Fax written comments on the collection of information by *[insert date 30 days after date of publication in the Federal Register]*.

**ADDRESSES:** OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202-395-6974.

**FOR FURTHER INFORMATION CONTACT:** Denver Presley, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1472.

oc0669

N2

**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 Health Care Practitioners Regarding Their Preferences for Public Health Notifications (PHNs)**

The PHN is one of the tools that the Center for Devices and Radiological Health (CDRH) uses to get an important message to the user community about risks associated with the use of medical devices. This particular tool is meant to serve a specific purpose not served by the other communication tools at our disposal—to be a source of information for health care practitioners, immediately recognizable as a statement from FDA, about a device risk with information on how to avoid or mitigate the risk. The purpose of this project is to evaluate the current notification format and distribution process for CDRH, with the goal of determining what is necessary to assure that the notifications reach, and are acted upon by, the target audience. The center needs to know that it is using the most effective approach to formatting and to disseminating PHNs to assure that they are received, recognized, understood, and acted upon quickly and effectively by medical practitioners and institutions. Considerations include, but are not limited to, design, terminology, nomenclature, distribution, utility of standardization, relationship with other medical product notifications (e.g., recalls), use of electronic transmission, and use of plain language.

The intent of this project is to determine the preferences of the health care community for learning from FDA about risks associated with medical devices and to compare the current process against the approach identified by the research to be “preferred” with the intent of improving our format and process.

CDRH will conduct a survey of a sample of health care providers who receive a new PHN from FDA. Most recently, FDA has been using intermediary organizations, such as professional associations, to help us distribute notifications to the appropriate target audiences and we are assuming that any new PHN will be disseminated in this way, using the appropriate association to distribute the PHN to their members. Generally, the PHN is distributed to the target audience electronically, either as a link embedded in a news article or sent directly via e-mail from either the professional association or FDA using the e-mail listing provided by the professional association. As part of the notification, we will provide a link to a Web-based questionnaire that will collect information related to the health care providers' preferences for learning about risks associated with medical devices.

The information collected in this survey will help FDA identify the most effective format(s) and distribution method(s) for CDRH PHNs.

In the **Federal Register** of January 9, 2006 (71 FR 1428), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

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

Activity	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Survey of health care providers in relevant specialty	300	1	300	.1666	50
Survey of health care providers in another relevant specialty	300	1	300	.1666	50
Total					100

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

Public reporting burden for this collection of information is estimated to average 10 minutes per response, including the time for reviewing instructions and completing the questionnaire.

Dated: 3-22-06  
March 22, 2006.

*Jeffrey Shuren*

Jeffrey Shuren,  
Assistant Commissioner for Policy.

[FR Doc. 06-????? Filed ??-??-06; 8:45 am]

BILLING CODE 4160-01-S

CERTIFIED TO BE A TRUE  
COPY OF THE ORIGINAL  
*Dawn P. Hawkins*