

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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Officer	L. CLAWSON
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Agency Emergency Processing Under the Office of Management and Budget Review; MedWatch—The Food and Drug Administration Safety Information and Adverse Event Reporting Program; Proposal to Survey MedWatch Partners Organizations

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 emergency processing under the Paperwork Reduction Act of 1995 (the PRA). This notice solicits comments on a proposal for the MedWatch program to deploy and conduct a web-based customer satisfaction survey of certain health care professional trade and specialty organizations that voluntarily have chosen to participate in the FDA MedWatch's Partners program. The survey will solicit information about the utility of the FDA MedWatch safety alerts and monthly safety labeling changes that are posted on the MedWatch Web site and disseminated to partner organizations for sharing with members of the organizations.

DATES: Fax written comments on the collection of information by *[insert date 30 days after date of publication in the Federal Register]*. FDA is requesting approval of this emergency processing 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 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: Karen Nelson, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1482.

SUPPLEMENTARY INFORMATION: FDA has requested emergency processing of this proposed collection of information under section 3507(j) of the PRA (44 U.S.C. 3507(j)) and 5 CFR 1320.13. This information is needed immediately so that the agency can effectively assess and re-evaluate its FDA MedWatch risk communication efforts in drug safety as part of a broader center level (the Center for Drug Evaluation and Research (CDER)) reorganization action to enhance its risk communication activities for CDER-regulated products, and address public expectations for timely dissemination of clinically useful safety information to both providers and their patients at the point of care.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through

the use of automated collection techniques, when appropriate, and other forms of information technology.

MedWatch—The FDA Safety Information and Adverse Event Reporting Program; Proposal to Survey MedWatch Partners Organizations

The MedWatch Partners program is an FDA outreach effort directed at health care provider professional organizations. The effort facilitates the timely dissemination of clinically important new safety information on the drugs, devices, and other human medical care products regulated by FDA and prescribed, dispensed, or used by the membership of these professional societies. In voluntarily agreeing to work with FDA MedWatch, these partner organizations disseminate this important safety information to their members and their members' patients so that medical products necessary to efforts to improve a patient's health may be used more safely and reduce the risk of harm.

Risk communication is one of the essential elements in the risk management paradigm accepted as a framework within CDER since described in the "Report to the FDA Commissioner from the Task Force on Risk Management" in May 1999. As an agency that regulates a broad range of clinical medical products—drugs, therapeutic biologics, blood products, medical devices, and dietary supplements—FDA's public health mission includes the timely dissemination of new safety information identified during post-marketing surveillance activities. This information includes class 1 recalls, public health advisories, notice of counterfeit drug product, and labeling changes such as new black box warnings or contraindications to drug product use. In recent years, there has been a public commitment to actively disseminating this new safety information, both to health care providers and their patients, and to leveraging this risk communication activity by developing

partnerships and alliances with non-governmental organizations. This commitment was explicitly identified as an objective in the strategic plan for “Improving Patient Safety” of former Commissioner of Food and Drugs, Mark McClellan. That objective states that FDA will “take appropriate actions to communicate risks and correct problems associated with medical products” and “will identify new ways to inform physicians, pharmacists, nurses, and patients about the safety of FDA-regulated products.”

The MedWatch program is currently located in the Office of Drug Safety, CDER. MedWatch disseminates safety information on FDA-regulated medical products to both health care professional and consumer/patient audiences. MedWatch maintains a comprehensive Web site at <http://www.fda.gov/medwatch> for this purpose. The FDA MedWatch program has about 120 Partner organizations that represent clinical care providers (doctors, nurses, pharmacists, etc.). As a “Partner,” the organization has agreed to support the goals of the MedWatch program: Participating in the dissemination of FDA-approved safety information and promoting the voluntary reporting to FDA of adverse events. In order to communicate quickly with MedWatch Partner organizations, a listserv, supported by the National Institutes of Health, is maintained, with contacts for each MedWatch Partner group. Partner organizations have voluntarily agreed to receive these FDA MedWatch safety alerts and monthly safety labeling changes. Each organization receives e-mail notification of two types of FDA MedWatch safety information at the time it is added to the MedWatch Web site—safety alerts for individual products and, once a month, a listing of the 30 to 60 drugs that have had safety labeling changes for that month.

The FDA MedWatch program, in order to implement this safety information dissemination process effectively, needs to evaluate satisfaction of these customer groups so that FDA MedWatch can improve the dissemination process and content of this safety information and increase its use and application to direct patient care and to the public's health.

The purpose of the survey is to fulfill phase one of Executive Order 12862, "Setting Customer Service Standards," which directs agencies to continually reform their management practices and operations to provide service to the public that matches or exceeds the best service available in the private sector. There is no duplication of effort. The MedWatch program is the only one planning to perform this survey. By actively gathering this survey information from MedWatch partner customers, the agency will achieve a better understanding customer satisfaction with this program, and be able to direct limited resources to produce an improved program that is most useful to both health care provider customers and, secondarily, their patients.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Partner Organizations	120	1	120	.5	60

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

This burden estimate of total hours was developed by using: (1) The number of known MedWatch partner health care organizations, (2) the number of times the survey will be deployed, and (3) the expected time to complete

the response based on internal pilot testing of the survey instrument at the agency.

Dated: APR 24 2006
April 24, 2006.



Jeffrey Shuren,
Assistant Commissioner for Policy.

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