

SURVEY OF FDA MEDWATCH PARTNERS ORGANIZATIONS

JUSTIFICATION

Docket No. 2006N-0166

1. **Circumstances That Make Information Collection Necessary**

Risk communication is one of the essential elements in the Risk Management paradigm accepted as a framework within the Center for Drug Evaluation and Research [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 – the 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 publicly-acknowledged attempt by the agency to proactively disseminating this new safety information, both to healthcare 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 FDA Commissioner 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, was previous located in the Office of Drug Safety (ODS), Center for Drug Evaluation and Research (CDER). As part of the new CDER drug safety initiative and reorganization announced November 2005 by CDER Center director, Dr. Steven Galson, the MedWatch program was relocated as of May 2006 to the Office of the Center Director, as part of the newly formed staff of the Associate Center Director of Safety Policy and Communication.

MedWatch disseminates safety information on FDA-regulated medical products to both healthcare professional and consumer/patient audiences. MedWatch maintains a comprehensive website [home page: www.fda.gov/medwatch] for this purpose. The FDA MedWatch program has about 120 Partner organizations, a subset of all Partner organizations, that represent clinical care providers [doctors, nurses, pharmacists, etc.]. As a "Partner", each 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 listserve, supported by the NIH, 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 website – safety alerts for individual products and, once a month, a listing of the 30-60 drugs that have had safety labeling changes for that month.

2. Purpose of Information Collection

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. 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 healthcare provider customers and, secondarily, their patients

3. Use of Improved Information Technology

There are no technical or legal obstacles to the use of improved information technology to reduce the burden of reporting this information. The survey will be developed and deployed using a web-based survey application that should allow voluntary respondents to report the requested information more easily and reliably.

4. Efforts to Identify Duplication and Availability of Similar Information

There is no duplication of effort. The MedWatch program expects to only perform this survey of this audience/customer on one occasion. This information, or any similar information, is not available elsewhere.

5. Small Business Considerations

This one-time survey of existing MedWatch Partner organizations has no special small business considerations.

6. Consequences of Less Frequent Information Collection

The FDA MedWatch program, in order to implement its safety information dissemination responsibilities effectively, needs to evaluate satisfaction of these customer groups so that FDA MedWatch can improve both the dissemination process and the content/format of this safety information. Without this information for evaluation and program planning, the dissemination of FDA-approved safety information will be less effective and the potential for safer use of FDA-regulated human healthcare products will be diminished.

7. Special Circumstances That Require Departures from 5 CFR 1320.5

The specific reporting and recordkeeping timeframes are justified in the respective regulatory approvals.

8. Efforts to Consult with Non-Agency Personnel

In a May 1, 2006 Federal Register notice (FR Doc. E6-6461) announcing the proposed survey of the FDA MedWatch professional Partners organizations, the FDA invited comments on the collection of information, specifically: (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.

No comments were received to the docket during the thirty day comments period.

9. Payment or Gifts

FDA will provide no payment or gift to any respondent organization except a certificate of appreciation for completing the web-based survey.

10. Assurances of Confidentiality

The HIPAA Privacy Rule recognizes the legitimate need for public health authorities and others responsible for ensuring public health and safety to have access to protected health information to carry out their public health mission. [DISCLOSURES FOR PUBLIC HEALTH ACTIVITIES, *45 CFR 164.512(b)*] The Rule also recognizes that public health reports made by covered entities are an important means of identifying threats to the health and safety of the public at large, as well as individuals. Accordingly, the Rule permits covered entities to disclose protected health information without authorization for specified public health purposes. Covered entities may disclose protected health information to a person subject to FDA jurisdiction, for public health purposes related to the quality, safety or effectiveness of an FDA-regulated product or activity for which that person has responsibility. Examples of purposes or activities for which such disclosures may be made include, but are not limited to:

- < Collecting or reporting adverse events (including similar reports regarding food and dietary supplements), product defects or problems (including problems regarding use or labeling), or biological product deviations;
 - < Tracking FDA-regulated products;
 - < Enabling product recalls, repairs, replacement or look back (which includes locating and notifying individuals who received recalled or withdrawn products or products that are the subject of look back);
- and

< Conducting post-marketing surveillance.

The “person” subject to the jurisdiction of the FDA does not have to be a specific individual. Rather, it can be an individual or an entity, such as a partnership, corporation, or association.

11. Additional Assurances of Privacy

No questions of a private or sensitive nature are asked. All inquiries are about characteristics of the organization and none are individual personal health questions.

12. Estimates of the Burden Collection

The estimated annual reporting burden for this information is 48 hours

ESTIMATED ANNUAL REPORTING BURDEN

Partner Organizations	No. of Respondents	Expected response rate	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
	120	80 %	1	96	0.5	48

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 healthcare 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. Our expectation with this audience and using the described survey process is to have, at minimum, an 80% response rate.

The information collection costs imposed on the individual Partner organization is estimated as follows:

The monetized burden hours is estimated at \$3408, [calculated at \$71/hour/respondent x 30 minutes/response x 120 respondents x est. 80% response rate] using the wage rate found in BOL statistics at <http://www.bls.gov/oes/current/oes119111.htm> with a 40% add-on for benefits.

13. **Cost to Respondents** none

14. **Cost to the Federal Government**

The estimated cost to the Federal Government for development, deployment and evaluation of this survey instrument is \$11,000.00

15. **Reason for Changes in Burden**

There is no previous baseline burden for comparison. This survey is a one-time collection of information.

16. **Plans for Statistical Use**

The information collected will not be used for statistical purposes. the plan is to present these study results only internally within CDER/FDA at a forum; there are no plans to publish/release the results to the public. These results are primarily for program design/evaluation purposes.

17. Approval for Not Displaying Expiration Date

FDA is not requesting approval for not displaying expiration date.

18. Exception to the Certification Statement; Item 19, OMB Form 83-1

FDA is not requesting an exception to the certification statement identified in Item 19 "Certification for Paperwork Reduction Act Submissions" of OMB Form 83-1.

