DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

Date May 5, 2010

From PRA Specialist, Paperwork Reduction and Records Management Staff
Office of Information Management

Subject Request for Approval of FDA Customer Satisfaction Survey, "MedWatch Safety Alert Email Service Customer Satisfaction Survey"-- OMB Control No. 0910-0360

To Human Resources and Housing Branch
Office of Information and Regulatory Affairs, OMB

Through HHS Reports Clearance Officer_____

The Food and Drug Administration (FDA), Office of the Commissioner/Office of External Affairs/Office of Special Health Issues is seeking OMB approval under the generic clearance 0910-0360 to conduct a customer satisfaction survey for the MedWatch Safety Alert Email Service. MedWatch disseminates safety information on FDA-regulated medical products to a target audience of healthcare professionals. The MedWatch alerts provide timely new safety information on human drugs, medical devices, vaccines and other biologics, dietary supplements, and cosmetics. The alerts contain actionable information that may impact both treatment and diagnostic choices for healthcare professionals and patients. MedWatch provides the safety information through a variety of communication mediums (i.e. Web, RSS, email listserv, text messaging) and has 156,000 subscribers to the gov.delivery email listserv.

The purpose of the survey is to obtain feedback from MedWatch email listserv users on (1) their current level of satisfaction with the information provided by MedWatch, and (2) their recommendations on how to improve information provided by MedWatch. FDA will use the data from this information collection only internally for general service improvement. Findings will not be used for publication or for the purpose of informing significant policy or resource allocation decisions.

Purpose of Information Collection, How and By Whom

The survey will fulfill phase one of Executive Order 12862, 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. Specifically, the Order calls for agencies to "survey customers to determine the kind and quality of services that they want and their level of satisfaction with existing services." MedWatch's goal is to effectively inform health care providers about safe-use of medical

products. To do this, FDA must first understand how customers feel about the current MedWatch Safety Alert emails. By actively gathering this survey information from MedWatch customers, the agency will achieve a better understanding of customer satisfaction with this program.

FDA will collect and use information to identify strengths and weaknesses in the current provisions of service. Customers will be asked to assess the usefulness, appropriateness, preferred format of MedWatch email content. If this information is not collected, vital feedback regarding key customers' satisfaction or dissatisfaction with various aspects of FDA program services will be unavailable.

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.

Efforts to Identify Duplication and Availability of Similar Information

This information, or any similar information, is not available elsewhere. If future administrations of the survey are necessary, FDA will return to OMB for additional clearance.

Consequences of Less Frequent Information Collection

In order to implement its safety information dissemination responsibilities effectively, FDA needs to evaluate satisfaction of these customers. 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.

Payment or Gift

FDA will not provide incentives to respondents.

Confidentiality Provisions

The privacy of respondent identification and information will be assured to the maximum extent allowed by law. Participation will be fully voluntary and responses will be anonymous. Respondents will be assured that neither their participation/non-participation, nor any responses to items, will affect their eligibility to receive FDA services.

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.

Plans for Statistical Use

Customer satisfaction surveys approved under this generic clearance will not yield meaningful quantitative findings; they can provide useful customer input, but they do not yield data about customer opinions that can be generalized. Findings will be used to obtain information for general service improvement, not for publication or for the purpose of informing significant policy or resource allocation decisions.

Burden of Information Collection

The survey will be administered via email to a random sample of 5,000 MedWatch subscribers who will be provided a link to complete the survey on-line. The estimated maximum time required to participate in the survey is 5 minutes. A total of no more than 5,000 MedWatch customers will be invited to take the survey. Not all respondents will be asked all survey questions. Survey respondents will be immediately asked two screener questions that take an estimated 30 seconds to complete. Respondents not part of the intended audience (i.e., healthcare professionals working in medical or pharmacy settings) will be automatically skipped to the end of the survey. FDA estimates that approximately 11% (455) of survey responders will only have to answer these two brief screener questions. This estimate is based on FDA's examination of a random sample of 200 MedWatch listserv email addresses, 11% of which appear to represent industry or financial investment firms that are not part of the intended audience. The table below shows an estimated total response burden of 381 hours.

Estimated Annual Reporting Burden				
Type of Respondent	No. of Respondents	Annual Frequency per Response	~~Hours~~ Minutes per Response~~s~~	Total Hours
Listserv subscribers not part of the intended audience	455	1	~~0.008~~5 (.083)	~~3.64~~38
Listserv subscribers working as healthcare professionals working in medical or pharmacy settings	4545	1	~~0.083~~5 (.083)	377~~.24~~
TOTAL	5000			~~381~~415*

* The total hours of 380.88 has been rounded to the next highest integer.

Costs to Respondents

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

Costs to Federal Government

The cost for use of the web-based survey software would cost the agency approximately $200 annually.

Display of OMB Approval Date

We are requesting no exemption.

Exceptions to Certification for Paperwork Reduction Act Submissions

These activities will comply with the requirements in 5 CFR 1320.9.

B. Statistical Methods

Potential Respondent Universe

FDA MedWatch has identified the respondent universe for this program as the 156,000 subscribers to the FDA MedWatch gov.delivery subscriber listserv. From this listserv, a random sample of 5,000 subscribers will be invited to take the survey. Because FDA does not know many characteristics of its MedWatch customers, a sample of 5,000 is projected to provide sufficient details about population subgroups while at the same time limiting the burden of the subscriber population.

FDA MedWatch has designed the survey to minimize burden on respondents while obtaining essential information. The expectation is that information collection instruments will require no more than 5 minutes response time, on average.

Information Collection Procedures

FDA will conduct all data collection in a way that is consistent with the following principles:

- Participation will be fully voluntary, and non-participation will have no impact on eligibility for or receipt of future services.

- Information to be collected will be limited to that needed to assess customer satisfaction.
- FDA will attempt to obtain the highest possible response rates, given the voluntary nature of the data collection efforts.

Methods to Maximize Response Rates

The population for this survey consists of self-subscribers to MedWatch email alerts; FDA anticipates the subject of this survey will be of particular interest to this audience. However, the design of the survey will include approaches to maximize response rates, while retaining the voluntary nature of the effort.

- Potential respondents will be informed in the invitation about the importance of the survey and encouraged to participate
- Emails will only be resent to those who do not open or click the link to the survey in previous attempts. The first notification will be sent in week 1, a second notification sent in week 2, and a third and final notification in week 3. Please see the attachment for the language that will be sent in the body of the email.
- A progress bar will display at the top of the survey in order to minimize burden and responders will see it is a relatively quick survey.
- The survey will be open for a total of 4 weeks. This timeframe will allow the survey to reach individuals who are on vacation or who have limited access to email.
- Potential respondents will be encouraged to contact MEDWATCHCOMMENTS@FDA.HHS.GOV should they have any questions about the survey's legitimacy.

Test of Procedures

The development of the survey included a team approach and solicited expertise from communication specialists. We administered pre-testing to less than 7 internal FDA customers, with debriefing of pre-test respondents as needed to clarify responses.

Statistical Consultation

The FDA clearance office works closely with statisticians with expertise in survey methodology and questionnaire design, and familiarity with principles of sampling and data analysis from the Office of Planning. This statistical expertise will be available from agency statisticians or from contractors. If needed, FDA will arrange for technical assistance in statistics and survey design through the National Center for Health Statistics. In this case we sought consultation from the statisticians and recognize this is not a statistical survey.

Attachment: (3)

1. Executive Order 12862
2. Survey Questions
3. Email message