DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

Date

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

Subject Request for Approval of FDA Customer Satisfaction Survey, "CDER Drug Risk Information 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), Center for Drug Evaluation and Research is seeking OMB approval under the generic clearance 0910-0360 to conduct a customer satisfaction survey entitled, "CDER Drug Risk Information Survey", to provide FDA with feedback from individuals visiting CDER's website to obtain drug risk information. This project will enable us to evaluate the current format, presentation and content of drug risk communication tools (Public Health Advisories, Information for Healthcare Professionals, Early Communication about an Ongoing Safety Review and the Drug Safety Newsletter), with regard to their appropriateness to the target audiences.

The Center needs to know that it is using the most effective approach to formatting and presentation, and that content that is accessible to the reader. Considerations include, but are not limited to, format and presentation, including ease of reading, ease of locating information, organization of information, font and font size, length; and content, including relevance of content to specialty or area of expertise, understandability of content, timeliness of content, helpfulness of content, amount of background information

The purpose of the survey is to fulfill phase one of Executive Order 12862 that requires Federal Agencies to "survey customers to determine the kind and quality of services that they want and their level of satisfaction with existing services." FDA will collect and use the information gathered from the survey to identify strengths and weaknesses of the specific drug risk communication tools and ease in accessing this information from FDA's website and to make practical and feasible improvements to the tools and/or website. Information gathered from surveying Website users will enable the agency to provide effective and efficient feedback. Important feedback regarding customers' satisfaction or dissatisfaction with the drug risk communication tools and website will not be available if this information is not collected. Consequently, FDA will be unable to determine if its efforts to improve how healthcare professionals, patients and consumers access, and understand drug risk information are successful or need revision. One of the goals of this research is to determine the preferred approach for notifying the general public and health care community about drug risk information. Using the information that FDA intends to receive from this survey, coupled with experience and good risk communication principles, we hope to identify the most effective format(s) and content for communicating drug safety information.

The intended data-collection will be conducted through an on-line (Web-based) survey. We will

use all of our drug risk communication tools; they will be disseminated via MedWatch and made otherwise accessible according to our current procedures. The survey will be applied as "pop-ups" within a particular communication vehicle when a user accesses that tool. The survey will remain available until such time that we obtain responses from 1000 individuals accessing any of CDER's drug risk communication tools.

The survey will be conducted by CDER. The information will be collected once.

Estimated Annual Reporting Burden				
Type of Survey	No. of Respondents	Annual Frequency per Response	Hours per Responses	Total Hours
Website usability survey	1,000	1	.083	83.3

The request is to obtain feedback from healthcare professionals, patients and consumers who visit FDA's website. In spite of the fact FDA's Website, as a whole, gets thousands of visitors, we do not have experience in knowing what percentage of such visitors would provide feedback. Once we have experience with getting feedback using this method, we should be in a better position to extrapolate the length of time needed a little more confidently. We estimate that it will take approximately 5 minutes to complete the survey. We will close the survey after we obtain 1000 respondents.

There will be no tabulated results for this information collection. Website usability surveys approved under this generic clearance will not yield meaningful quantitative findings. While they can provide useful input from our stakeholders, they will not yield data on opinions that can be generalized. The findings will be used to obtain information for more general improvement, not for publication or for the purpose of informing significant policy or resource allocation decisions.

If you have any questions, please contact Elizabeth Berbakos at 301.796.3792 or Elizabeth.Berbakos@fda.hhs.gov.

Attachments: Access to Survey Questions – Access to the survey is provided via the link below

http://vovici.com/wsb.dll/s/2ff9g39c6f