Customer/Partner Customer Satisfaction Service Surveys
OMB Control Number -- 0910-0360
SUPPORTING STATEMENT

A. Justification

1. Circumstances Making the Collection of Information Necessary

Executive Order 12862 directs Federal agencies to provide service to the public that matches or exceeds the best service available in the private sector. In order to work continuously to ensure that our programs are effective and meet our customers' needs, The Food and Drug Administration (hereafter "FDA") seeks to obtain OMB approval of a generic clearance to collect qualitative feedback on our service delivery. By qualitative feedback we mean information that provides useful insights on perceptions and opinions, but are not statistical surveys that yield quantitative results that can be generalized to the population of study.

The Food and Drug Administration (FDA) is requesting that the Office of Management and Budget (OMB) extend approval of a generic clearance that implements Executive Order 12862 which directs agencies that "provide significant services directly to the public" to "survey customers to determine the kind and quality of services they want their level of satisfaction with existing services." FDA provides a wide range of services to the public and to the regulated industries. To fulfill this directive FDA is requesting a generic approval to conduct:

- customer service surveys of any regulated entities such as food processors, cosmetic, drug, biologic, medical device and tobacco manufacturers, consumers, health professionals, and State and local governments;
- web-based, remote-user feedback surveys to assess and improve the quality of information services that FDA provides through its website.

There are two objectives for these surveys in seeking ideas from respondents on (1) their current level of satisfaction with the services and information provided by FDA and (2) their recommendations on how to improve services and information provided by FDA.According to OMB guidelines for generic clearances for voluntary customer/partner service surveys, FDA will establish an independent review process to assure the development and implementation of high quality customer/partner service surveys within FDA. FDA will provide OMB a copy of the survey instrument for review and approval within 10 days and inclusion in the public docket.

This collection of information is necessary to enable FDA to garner customer and stakeholder feedback in an efficient, timely manner, in accordance with our commitment to improving service delivery. The information collected from our customers and stakeholders will help ensure that users have an effective, efficient, and satisfying experience with FDA's programs. This feedback will provide insights into customer or stakeholder perceptions, experiences and expectations, provide an early warning of issues with service, or focus attention on areas where communication, training or changes in operations might improve delivery of products or

services. These collections will allow for ongoing, collaborative and actionable communications between FDA and its customers and stakeholders. It will also allow feedback to contribute directly to the improvement of program management.

2. Purpose and Use of the Information Collection

FDA will collect and use information gathered through this vehicle to identify strengths and weaknesses in current service provisions, including FDA's website, and to make improvements that are practical and feasible. Information from these customer service surveys and website usability surveys will be used to plan and redirect resources and efforts to improve or maintain a high quality of service to affected publics. FDA's website provides a variety of services to the general public, health professionals, drug and biologics companies, consumer advocates, students, medical professionals, and journalists. Website usability will be surveyed on a regular basis on different parts of FDA's website. Information gathered from surveying website users will enable the agency to provide an effective, efficient, and satisfying experience. Timeliness, appropriateness, accuracy of information, courtesy, or problem resolution will be assessed in individual programs. If this information is not collected, vital feedback regarding customers' satisfaction or dissatisfaction with various aspects of FDA program services, including FDA's website, will be unavailable.

The generic clearance will only be used for customer satisfaction and website usability surveys where FDA seeks to gather information that is planned for internal use only, and can provide a justification for qualitative or anecdotal collections that may nonetheless produce useful information for program and service improvement. Customer satisfaction surveys approved under the generic clearance will only be used to obtain information for general service improvement, not for publication or for the purpose of informing significant policy or resource allocation decisions. In addition, individual collections will concern subject matter and methods that are not controversial. FDA website usability data will be collected to ensure that we have the valuable data needed to routinely revise content and reorganize important online health and consumer information in a way that is most easily understood and useful to by the website visitors.

Improving agency programs requires ongoing assessment of service delivery, by which we mean systematic review of the operation of a program compared to a set of explicit or implicit standards, as a means of contributing to the continuous improvement of the program. FDA will collect, analyze, and interpret information gathered through this generic clearance to identify strengths and weaknesses of current services and make improvements in service delivery based on feedback. The solicitation of feedback will target areas such as: timeliness, appropriateness, accuracy of information, courtesy, efficiency of service delivery, and resolution of issues with service delivery. Responses will be assessed to plan and inform efforts to improve or maintain the quality of service offered to the public. If this information is not collected, vital feedback from customers and stakeholders on FDA's services will be unavailable.

FDA will only submit a collection for approval under this generic clearance if it meets the following conditions:

- The collections are voluntary;
- The collections are low-burden for respondents (based on considerations of total burden hours, total number of respondents, or burden-hours per respondent) and are low-cost for both the respondents and the Federal Government;
- The collections are non-controversial and do not raise issues of concern to other Federal agencies;
- Any collection is targeted to the solicitation of opinions from respondents who have experience with the program or may have experience with the program in the near future;
- Personally identifiable information (PII) is collected only to the extent necessary[1] and is not retained;
- Information gathered will be used only internally for general service improvement and program management purposes and is not intended for release outside FDA (if released, procedures outlined in Question 16 will be followed);
- Information gathered will not be used for the purpose of substantially informing influential policy decisions[2]; and

Information gathered will yield qualitative information; the collections will not be designed or expected to yield statistically reliable results or used as though the results are generalizable to the population of study.

1 All privacy act requirements will be met.

2 As defined in OMB and agency Information Quality Guidelines, "influential" means that "an agency can reasonably determine that dissemination of the information will have or does have a clear and substantial impact on important public policies or important private sector decisions."

3. Use of Improved Information Technology and Burden Reduction

As appropriate, automated information technology will be used to collect and process information for these surveys to reduce the burden on the public. Surveys will be simple with short questions.

4. Efforts to Identify Duplication and Use of Similar Information

No similar data are gathered or maintained by FDA or are available from other sources known to FDA.

5. Impact on Small Businesses or Other Small Entities

Small business or other small entities may be involved in these efforts but FDA will minimize the burden on them of information collections approved under this clearance by sampling appropriately, asking for readily available information, and using short, easy-to-complete information collection instruments.

6. Consequences of Collecting the Information Less Frequently

Without feedback about its service delivery, FDA will not have timely information to adjust its services to meet customer needs.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances. The information collected will be voluntary and will not be used for statistical purposes.

8a. Comments in Response to the Federal Register Notice

In accordance with 5 CFR 1320.8(d), on January 13, 2011 (73 FR 2395), a 60-day notice for public comment was published in the FEDERAL REGISTER. No comments were received.

8b. Efforts to Consult Outside the Agency

FDA programs will use routine contacts with customers and partners and other qualitative information collection activities to identify areas of interest and concern to customers and partners. FDA will utilize in-house statistical staff and the staff of contractors in developing survey plans. As needed, FDA may also utilize the statistical resources of the National Center for Health Statistics, which has a questionnaire design laboratory. As appropriate, centers will establish panels of outside experts to help in design and implementation of the surveys.

9. Explanation of Any Payments or Gift to Respondents

FDA, as a rule, will not provide payment or other forms of remuneration to respondents of its various forms of collecting feedback on customer satisfaction.

In the case of in-person interview requiring travel, any proposed stipend needs to be justified to OMB. Normally, a stipend of $40 will be provided. If such information collections include hard-to-reach groups and FDA plans to offer non-standard stipends, FDA will provide OMB with additional justifications in the request for clearance of these specific activities. If OMB guidance for the stipend level is adjusted upward, the stipends may also be increased accordingly.

10. Assurance of Confidentiality Provided to Respondents

Information provided by respondents will be kept private and anonymous, except as otherwise required by law. This will be communicated to respondents by means of introductory letters, explanatory texts on the cover pages of questionnaires, scripts read prior to telephone interviews, and consent forms. Respondents also will be advised of the following: the nature of the activity; the purpose and use of the data collected; FDA sponsorship (when appropriate[3]); and the fact that participation is voluntary at all times. Because responses are voluntary, respondents will be assured that there will be no penalties if they decide not to respond, either to the information collection as a whole or to any particular questions.

Only personnel from a contractor conducting the information collection will have access to individual-level survey or interview data. All project staff from a contractor conducting the information collection must take required measures to ensure the privacy and anonymity of data. Personally identifiable data shall be limited to information that may be required in the process of respondent enrollment. Personally identifiable information will be accessible to only those contractors who need them and will not be linked to interview data. All personally identifiable data will be destroyed at the completion of the study. Neither FDA employees nor any federal employee of any other Agency will have access to this information.

All electronic and hard-copy data will be maintained securely throughout the information collection and data processing phases. While under review, electronic data will be stored in locked files on secured computers; hard-copy data will be maintained in secure building facilities in locked filing cabinets. As a further guarantee of privacy and anonymity, all presentation of data in reports will be in aggregate form, with no links to individuals. Reports will be used only for research purposes and for the development of communication messages.

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3 In some cases, FDA sponsorship will not be made known to respondents prior to data collection out of concern for the potential introduction of bias to study results. In such cases, FDA sponsorship will be made known after the data are collected.

Communications testing efforts are typically considered exempt from the "Regulations for the Protection of Human Subjects" in accordance with paragraph (b)(3) of 45 CFR Sec. 46.101). Before data are collected, FDA researchers must obtain either an exemption or a full approval for all research from FDA's IRB, the Research Involving Human Subjects Committee.

Minors (or children) are persons who have not attained the legal age for consent to treatments or procedures described in the study are covered under the applicable law of the jurisdiction in which the research will be conducted. Where FDA's IRB determines that minors are capable of giving an assent, the IRB shall determine whether adequate provisions are made for soliciting assent. Generally, assent requires securing the signature of a minor to the research in a separate assent form, in addition to the consent form the parent or legal guardian signs. An assent document should contain an explanation of the study, a description of what is required of the subject (e.g., what they will experience (whether the interview will take place, whether the child's parents will be with him or her, etc.)), an explanation of any risks or mental anguish associated with the study, and an explanation of the benefits to the child or others.

11. Justification for Sensitive Questions

No questions will be asked that are of a personal or sensitive nature.

12a. Estimates of Annualized Burden Hours

The total annual estimated burden imposed by this collection of information is 7,500 hours annually.

Estimated Annual Reporting Burden					
Type of Survey	No. of Respondents	No. of Responses per Respondent	Total Annual Respondents	Average Burden per Response	Total Hours
Mail, telephone, in person, fax and web-based surveys and questionnaires	15,000	1	15,000	.25 (15 minutes)	3,750
Website usability surveys	15,000	1	15,000	.25 (15 minutes)	3,750
Total					7,500

12b. Annualized Cost Burden Estimate

There are no costs to the respondents.

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

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

14. Annualized Cost to the Federal Government

Staff or Contractor	*Average Hours per Study*	*Average Hourly Rate*	*Average Annual Cost*
Contractor instrument preparation, conduction, analysis (GS-12/GS-13 FTE)	20	$45.31	$906.20
FTE survey preparation, conduction, analysis (GS-13)	20	$49.22	$984.40
FTE manager survey review (GS-14)	5	$58.17	$290.85
Total			**$2,181.45**

15. Explanation for Program Changes or Adjustments

The increase (adjustment) in burden hours is due to an increasing number of customer satisfaction surveys FDA has conducted over the past 18 months.

16. Plans for Tabulation and Publication and Project Time Schedule

Feedback collected under this generic clearance provides useful information, but it does not yield data that can be generalized to the overall population. Findings will be used for general service improvement, but are not for publication, other public release, or for the purpose of informing significant policy or resource allocation decisions.

Although FDA does not intend to publish its findings, it may receive requests to release the information (e.g., congressional inquiry, Freedom of Information Act requests). FDA will disseminate the findings when appropriate, strictly following FDA's "Guidelines for Ensuring the Quality of Information Disseminated to the Public," and will include specific discussion of the limitation of the qualitative results discussed above.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

The agency is not requesting an exemption.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

Not applicable.