A. **Justification**

1. **Circumstances Necessitating Information Collection**
   The Food and Drug Administration (FDA) is requesting Office of Management and Budget (OMB) extend the approval of a generic clearance that implements Executive Order 12862. This request covers customer service surveys of any regulated entities such as Food Processors, Cosmetic, Drug, Biologic and Medical Device manufacturers as well as consumers and health professionals and partner surveys of the State and local governments.

   Executive Order 12862 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. Many of these services are focused on information dissemination activities mandated by legislation that are addressed to the public, regulated industries and health professionals.

   The purpose of the partner survey portion of this submission is to obtain generic approval for service surveys of our partners with various aspects of the “partnership” and to identify ways in which we can improve our service to and relations with them. Centers within FDA have provided a list of their respective proposed customer and partner satisfaction surveys (Attachment A).

   Consequently, there likely will be 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 inclusion in the public docket.

2. **How, By Whom, Purpose of Collection**
   FDA will collect and use information gathered through this vehicle to identify strengths and weaknesses in current service provisions and to make improvements that are practical and feasible. Information from these customer surveys will be used to plan and redirect resources and efforts to improve or maintain a high quality of service to effected publics. 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 will be unavailable.
3. Consideration Given to Information Technology
   As appropriate, automated information technology will be used to collect and process
   information for these surveys to reduce the burden on the public. Usually, however, the most
   appropriate methodology will involve written or oral responses to brief questionnaires.

4. Identification of Information
   Only limited information on customer/partner satisfaction with FDA services has been
   collected in the past. In order to completely fulfill the mission of the agency, implementation
   of E.O. 12862 will represent collection of new information for new purposes.

5. Small Businesses
   Small businesses or other small entities may be involved in these efforts, but FDA will keep
   the burden on them to a minimum by sampling, asking for opinions on a strictly voluntary
   basis, and the questionnaires will be short, user friendly and take a relatively short time to
   complete. Therefore, these customer/partner service surveys will not have a significant
   impact on small business or other small entities.

6. Less Frequent Information Collection
   FDA will conduct surveys only at intervals considered appropriate to measure the impact of
   changes because of initial satisfaction surveys and to monitor the continued level of
   performance. Usually, the Agency likely will conduct a satisfaction survey annually after the
   establishment of a baseline. Collection on a less frequent basis than annually would reduce
   the practical utility of the information and inhibit the programs’ ability to monitor changes.

7. Information Collection Circumstances
   There are no special circumstances for the collection of the information.

8. Consultations with Persons Outside FDA
   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.

   In accordance with 5 CFR 1320.8(d), on September, 16, 1998, in Volume 63, No. 179, page
   49581, a 60-day notice for public comment (Attachment B) was published in the Federal
   Register. No comments were received from the public.

9. Payment or Gift
   No payment or gift will be provided to survey respondents.

The confidentiality of respondent identification and information will be assured to the maximum extent allowed by law. Participation will be fully voluntary and, to the extend possible, responses will be anonymous. In instances where we need respondent identity (e.g., for following up of non respondents, or for a longitudinal design), the information collection will fully comply with all aspects of the Privacy Act. A data collection contractor will generally maintain any identifying information, and they will not give it to the agency. Respondents will be assured that neither their participation/non-participation nor any responses to items will affect their eligibility for or receipt of any FDA receipt.

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

12. **Burden of Information Collection**
   The total annual estimated burden imposed by this collection of information is 6,000 hours annually.

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<th>Estimated Annual Reporting Burden</th>
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<tbody>
<tr>
<td>Type of Survey</td>
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<td>Mail/telephone surveys/in person surveys and questionnaires</td>
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Surveys: FDA projects 16 customer and/or partner surveys per year, with a sample of between 50 and 6,000 customers which results in an average burden of 18 minutes per response. After the first year, some of these surveys may need to be repeated. We have allowed burden for unplanned surveys to be completed so as not to restrict the agency’s ability to obtain feedback on it’s performance in fulfilling it’s mission.

13. **Costs to Respondents**
   There are no capital costs or operating and maintenance costs associated with this collection.

14. **Costs to Federal Government**
   The postage paid postal response cards would cost the agency approximately $6,400 annually.

15. **Reason for Change**
   The agency plans to conduct more detailed surveys (requiring a longer completion time) targeting a more specific audience per survey. In order to meet the requirements of E.O. 12862 and in the course of fulfilling the Agency’s mission of protecting public health, feedback on performance is critical.

16. **Statistical Reporting**
   There are no tabulated results for this information collection.
17. **Display of OMB Approval Date**
   We are requesting no exemption.

18. **Exceptions to “Certification for Paperwork Reduction Act Submissions”**
   These activities will comply with the requirements in 5 CFR 1320.9.

**B. Statistical Methods**

1. **Potential Respondent Universe and Sample Selection Method**

   FDA will separately identify the respondent universe for each program whose customers and partners will be surveyed. If needed, we will design developmental activities to assure inclusion of an appropriate range of customers and partners; will carry quantitative activities out using sampling procedures developed to be properly representative of the universe.

   Occasionally it will be necessary for all partners in a particular category to be surveyed. For example, FDA will survey grantees to determine satisfaction with technical assistance activities is likely to include all grantees whom we offered or received the assistance.

   FDA will design surveys to minimize burden on respondents while obtaining essential information. The expectation is that information collection instruments will require no more than 15 minutes response time, on average. Focus groups will generally last for 1 ½ hours.

   In nearly all instances, there will be existing lists of “customers/partners” readily available for sampling. For example, mailing lists for publications, recipients of particular materials or services within known customer groups. FDA will use appropriate probability sampling techniques to select samples.

2. **Information Collection Procedures**

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

   - When sampling is used, FDA will determine appropriate sample sizes for each activity to assure that burden is minimized while the surveys produce reliable estimates.

   - Participation will be fully voluntary, and non-participation will have no impact on eligibility for or receipt of future services. If necessary, FDA will take steps to ensure unbiased completion of questionnaires by us of third-party distribution and receipt by a party not directly involved in provision of the service being assessed.

   - Information to be collected will be limited to that needed to assess customer/partner satisfaction. Repeated implementation of quantitative surveys will be at an interval appropriate to measure the impact of changes and to monitor ongoing levels of satisfaction.
FDA will attempt to obtain the highest possible response rates, given the voluntary nature of the data collection efforts. To the extent feasible, we will attempt to assess non-response bias.

3. **Methods to Maximize Response Rates**

Consistent with sound survey methodology, the design of each quantitative survey will include approaches to maximize response rates, while retaining the voluntary nature of the effort. For mail surveys, for example, FDA expects that this included a postcard follow up, a second mailing of the questionnaire, and possibly some telephone follow up, if phone numbers are readily available.

4. **Test of Procedures**

FDA anticipates that most surveys will begin with focus groups or similar efforts to identify the views and concerns of customers/partners. We will carry out more formal pre-testing at a level and in a manner consistent with the specific survey. We expect that all mail and telephone surveys included pre-testing with a few customers/partners, with telephone debriefing of pre-test respondents as needed to clarify responses.

5. **Statistical Consultation and Independent Review**

Each program will obtain information from statisticians in the development, design, conduct and analysis of customer/partner service surveys. 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.

Program offices will develop and submit proposals for specific customer/partner service surveys within FDA to FDA for review and approval by the Office of Information Resources Management (OIRM). 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 and Evaluation (OPE).