United States Food and Drug Administration
Generic Clearance: Customer Satisfaction Surveys
OMB Control Number 0910-0360
Gen IC Request for Approval

Title of Gen IC: CDRH Customer Satisfaction Survey

1. Statement of Need

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 and their level of satisfaction with existing services." The Food and Drug Administration (FDA) provides a wide range of services to the public and to regulated industries.

FDA's Center for Devices and Radiological Health (CDRH) is committed to delivering high-quality products and services to its customers. CDRH's ISO 9001:2015 certified Quality Management System (QMS) supports the Center's Mission and Vision. An ISO 9001:2015 certified QMS is required to be able to collect, document, and use voice of the customer input (customer satisfaction and customer experience) to assess effectiveness and improve the organization's products and services. It is a continuous strategic priority for CDRH to provide excellent customer service and deliver an exceptional customer experience. CDRH has in place "Standards of Excellence" and "Guiding Principles" that delineate expectations for interactions with stakeholders. Stakeholders include the medical device industry, academia, patient groups, health professionals, consumers and anyone that interacts with CDRH. CDRH needs voice of the customer tools to gather feedback and satisfaction about its stakeholders' experience with CDRH's products and services.

This generic information collection updates a previously granted generic clearance. The umbrella generic was renewed, and this IC is being reattached under the updated clearance.

Supporting references:

- CDRH Quality Management and Organizational Excellence Program: https://www.fda.gov/about-fda/center-devices-and-radiological-health/cdrh-quality-management-program
- CDRH Customer Service Standards of Excellence: https://www.fda.gov/files/about%20fda/published/CDRH-Standards-of-Excellence.pdf

2. Intended Use of the Information

The ability to gather this information from stakeholders helps enable CDRH to do the following:

- Determine customer satisfaction ratings associated with CDRH products and services,
- Understand customer experience,
- Monitor trends and feedback around specific product or service areas for satisfaction or dissatisfaction and opportunities to improve the product or service,
- Identify opportunities to improve the development and delivery of products and services and the associated customer service and experience, and
- Identify areas where additional training and/or resources may be necessary to improve products and services, provide excellent customer service, and/or an exceptional customer experience.

We plan to stratify the data by product or service, customer sector and, internally, by CDRH component. CDRH will examine the data periodically, take action, and report performance.[1]

3. Description of Respondents

Respondents will be surveyed voluntarily and, depending on the product or service, may include stakeholders both internal and external to FDA/CDRH—the medical device industry, academia, patient groups, health professionals, consumers, other federal agencies, and anyone else that interacts with CDRH and wants to provide feedback about their experience with our products and services.

4. How the Information is Collected

The information will be collected by FDA staff using online or in-person methods. For example, online methods include using an electronic surveying instrument made available in following ways:

- Survey link on FDA.gov,
- Survey link embedded in email salutations of CDRH staff or in CDRH meeting agendas, and
- Instructions for finding the survey link posted in meeting rooms, added to CDRH staff presentations to the public, and included in selected CDRH public communications.

5. Confidentiality of Respondents

Respondents may voluntarily provide contact information to be used for follow-up. In instances where respondents would like to follow up with CDRH regarding a process or service interaction, the survey instrument will provide the CDRH QM Customer service email as the point of contact CDRHCUSTOMERSERVICE@fda.hhs.gov. In addition, CDRH includes the following statement on the survey:

"Your participation / nonparticipation is completely anonymous and voluntary. Your responses do not affect your eligibility for receipt of any FDA services or products."

6. Amount and Justification for Proposed Incentive

None

7. Questions of a Sensitive Nature

None

8. Description of Statistical Methods

Standard statistical techniques for analyzing survey data will be used. Qualitative and quantitative approaches may include contingency tables, histograms, sentiment analyses and other approaches, as appropriate.

[1] Results of the survey are not for the purpose of informing significant policy or resource allocation decisions. Any public dissemination of the findings, when appropriate, will follow 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.

9. Burden

Based on the past participation, CDRH anticipates receiving about 3,000 survey responses per year, approximately 53% of the responses are from external customers. The survey takes 3-5 minutes per response to complete (250 burden hours/year).

Type of information collection/Category of Respondent	No. of Respondents	Participation Time (minutes)	Total Burden (hours)
Individuals or households, Local, State, Tribal, or Federal Government, Medical Device Industry, Academia, Patient Groups, Health Professionals, Consumers			
Customer Experience and Satisfaction Questions	1,500	5	125
Customer Survey	1,500	5	125
Total	3,000		250

10. Date(s) to be Conducted

- Product or service customer experience and satisfaction will be collected as the need arises. CDRH expects that these targeted surveys will be open for a short period of time (one to three months).

11. Requested Approval Date

November 2025

12. FDA Contacts

Program Office Contact	FDA PRA Contact
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