

FDA DOCUMENTATION FOR THE GENERIC CLEARANCE OF CUSTOMER SATISFACTION SURVEYS (0910-0360)

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.

TITLE OF INFORMATION COLLECTION: CDRH Advisory Committee Satisfaction Survey

DESCRIPTION OF THIS SPECIFIC COLLECTION

1. **Statement of need:**

It is a continued strategic priority for the Center for Devices and Radiological Health (CDRH) to Provide Excellent Customer Service. The center has in place “[Standards of Excellence](#)” to assure CDRH employees understand and interact with our stakeholders with those standards in mind. The CDRH Advisory Committee team needs a tool to gather satisfaction levels of our meeting participants/stakeholders both inside FDA/CDRH and external, including the medical device industry, academia, patient groups, health professionals, consumers and anyone that interacts with CDRH. This voluntary Satisfaction Survey enables CDRH to: (1) determine stakeholder satisfaction ratings; (2) identify and help monitor trends around specific areas of satisfaction or dissatisfaction; and (3) identify areas for process improvement and improve them.

2. **Intended use of information:**

CDRH plans to use the data collected to: (1) determine customer satisfaction ratings; (2) identify and monitor trends around specific areas of satisfaction or dissatisfaction and determine future actions needed for advisory committee meetings; and (3) identify areas for process improvement and improve them so stakeholders receive the service they expect from CDRH. We plan to and separate the data by stakeholder and examine to determine the satisfaction of our stakeholders.

3. **Description of respondents:**

Respondents take the survey voluntarily and include stakeholders both internal and external to CDRH/FDA—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 our advisory committee meetings via the survey tool on the web.

4. **Date(s) to be Conducted:**

October 2020 – September 31, 2022

5. **How the Information is being collected:**

The information is electronically collected using an electronic survey instrument (Survey Monkey). Links to the survey may be available on FDA.Gov, on advisory committee

meeting agendas and materials, and added to CDRH Presentations made during advisory committee meetings.

6. Confidentiality of Respondents:

No requests for personal information (names, email address, phone numbers, etc.) are made through this survey. In addition, CDRH will include the following statement on the survey instrument and/or instructions:

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

7. Amount and justification for any proposed incentive

None

8. Questions of a Sensitive Nature (Data will be kept private to the extent allowed by the law)

None

9. Description of Statistical Methods

Data analytics include the “out of the box” survey monkey statistics. In addition, data is exported to excel. Excel files will be analyzed manually.

BURDEN HOUR COMPUTATION (*Number of responses (X) estimated response or participation time in minutes (/60) = annual burden hours*):

Based on anticipated participation, CDRH anticipates receiving about 2,000 surveys a year, approximately 40% of the responses are from CDRH employees. The survey takes 3-5 minutes to complete (100 burden hours/year).

Type/Category of Respondent	No. of Respondents	Participation Time (minutes)	Burden (hours)
Individuals or households, Local, State, Tribal, or Federal Government, Medical Device Industry, Academia, Patient Groups, Health Professionals, Consumers	1,200	5	100

REQUESTED APPROVAL DATE: October, 2020

NAME OF PRA ANALYST & PROGRAM CONTACT:

Ila S. Mizrachi
Paperwork Reduction Act Staff
ila.mizrachi@fda.hhs.gov
301-796-7726

Abigail Corbin
Abigail.Corbin@fda.hhs.gov
301-796-9142
Sharon Davis (OCE)
SharonM.Davis@fda.hhs.gov
301-796-5717

FDA CENTER: Center for Devices and Radiological Health