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 Customer Satisfaction Survey

DESCRIPTION OF THIS SPECIFIC COLLECTION

1. **Statement of need:**

   It is a continuous strategic priority for the Food and Drug Administration's (FDA's) Center for Devices and Radiological Health (CDRH) to provide excellent customer service. The center has in place "Standards of Excellence" and "Guiding Principles" and works to assure CDRH employees understand and interact with our stakeholders with those standards and principles in mind. CDRH needs a tool to gather satisfaction levels associated with CDRH's products and services from stakeholders both inside FDA/CDRH and external, including the medical device industry, academia, patient groups, health professionals, consumers and anyone that interacts with CDRH. Voluntary customer satisfaction surveys enable CDRH to: (1) determine customer satisfaction ratings associated with CDRH products and services; (2) identify and help monitor trends around specific product or service areas of satisfaction or dissatisfaction; (3) identify areas for process improvement and improve them; and (4) identify areas where additional training and or resources may be necessary to provide excellent customer service.
   (This document updates a previously granted generic clearance.)

   Supporting references:
   - Link to CDRH's 2014/2015 Strategic Priorities, specifically where the initial commitment—which continues to this day— to "Provide Excellent Customer Service" which is posted on the FDA internet site: https://www.fda.gov/media/88017/download.
   - Link to the CDRH Customer Service Standards of Excellence: https://www.fda.gov/media/88055/download
   - Link to the Guiding Principles: CDRH Guiding Principles

2. **Intended use of information:**

   As noted in 1. above, CDRH plans to use the data collected to: (1) determine customer satisfaction ratings with CDRH products and services (For example, CDRH established an overall customer goal of at least a 90 percent customer satisfaction rating. This goal is independent of the product of service); (2) identify and monitor trends around specific products or services and areas of satisfaction or dissatisfaction and determine future actions needed to achieve the Center and or product- or service-specific customer service goals; (3) identify areas for process improvement and improve them so customers can

receive the service they expect from CDRH; and (4) identify product or service areas where additional training and or resources may be necessary in order to provide excellent customer service. We are planning to stratify the data by customer sector and, internally, by CDRH component. CDRH will examine the data periodically and report cumulative scores quarterly.

3. **Description of respondents:**

Respondents take the survey 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 our customer service performance via our survey tool on the web.

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

CDRH has been conducting a product/service agnostic Customer Satisfaction Survey since April 2014. Since the survey has been updated:

- February 2016 - June 2019: (reduced the number of open-ended questions from two to one, as respondents were providing duplicative input)
- July 2019: Improve data analytics, Likert scales were added to questions related to the adoption of CDRH "Standards of Excellence"
- December 2019: Incorporated CDRH Guiding Principles

We expect to make the product/service-agnostic survey available on an ongoing basis.

Feedback regarding satisfaction with a specific product or service will be sought as the need arises. CDRH expects to have those surveys open for a short period of time (one to three months)

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

The information is electronically collected using an electronic survey instrument (e.g., Survey Monkey). Links to the survey are available on FDA.Gov, on email salutations of CDRH staff, on CDRH meeting agendas, posted in CDRH conference rooms, added to CDRH staff presentations to the public, and included in selected CDRH public communications.

6. **Confidentiality of Respondents:**

No requests for submitter's personal information (names, email address, phone numbers, etc.) are made through CDRH customer satisfaction surveys. In instances where respondents would like to follow up with CDRH regarding an interaction, the survey 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 instruments and/or instructions:

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

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 statistics provided by commercial survey services available to FDA. In addition, data is exported to excel. Excel files are analyzed using FDA computers and internal tools such Tableau and Minitab.

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

   Based on the past participation, CDRH anticipates receiving about 3,000 survey responses a year, approximately 64% of the responses are from external customers. The survey takes 3-5 minutes to complete (250 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	3,000	5	250

REQUESTED APPROVAL DATE: November, 2021

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