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 Center for Devices and Radiological Health (CDRH) to Provide Excellent Customer Service. The center has in place "Standards of Excellence" and works to assure CDRH employees understand and interact with our stakeholders with those standards in mind. CDRH needs a tool to gather satisfaction levels of our stakeholders both inside FDA/CDRH and external, including the medical device industry, academia, patient groups, health professionals, consumers and anyone that interacts with CDRH. The voluntary Customer Satisfaction Survey enables CDRH to: (1) determine customer satisfaction ratings; (2) identify and help monitor trends around specific areas of satisfaction or dissatisfaction; (3) identify areas for process improvement and improve them; and (4) identify areas where additional training 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

2. **Intended use of information:**
   As noted in 1 above, CDRH plans to use the data collected to: (1) determine customer satisfaction ratings (Center Goal: at least 90% per six month period); (2) identify and monitor trends around specific areas of satisfaction or dissatisfaction and determine future actions needed to achieve the Center customer service goals; (3) identify areas for process improvement and improve them so customer can receive the service they expect from CDRH; and (4) identify areas where additional training 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, twice a year.

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 customer service performance via our survey tool on the web.

4. **Date(s) to be Conducted:**
   CDRH has been conducting the survey since April 2014. Since the survey updated twice:
   - 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 question related to the adoption of CDRH "Standards of Excellence"

5. **How the Information is being collected:**
   The information is electronically collected using an electronic survey instrument (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 personal information (names, email address, phone numbers, etc.) are made through this survey. In instances where respondents would like to follow up with CDRH regarding an interaction; the survey provides 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 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 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 2,000 surveys a year, approximately 60% of the responses are from CDRH employees. The survey takes 3-5 minutes to complete (167 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	2,000	5	167

REQUESTED APPROVAL DATE: July 8, 2019

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FDA CENTER: CDRH