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: Feedback on Patient Preference Information (PPI) and Patient-Reported Outcomes (PRO) Workshops

DESCRIPTION OF THIS SPECIFIC COLLECTION

1. **Statement of need:**

   We will be holding virtual (webcast only) public meetings on Patient Preference Information (9/29/20) and Patient-Reported Outcomes (9/30/20) and wish to evaluate the quality of the meetings so that we can properly plan future public engagement efforts around this topic. Our intent is to gauge the level of satisfaction with the current meetings, as well as elicit feedback and recommendations on how to improve future meetings to meet the needs of all attendees. We will not solicit other types of feedback from respondents.

2. **Intended use of information:**

   We intend to use this information within CDRH to improve our future public meetings.

3. **Description of respondents:**

   Only attendees of the PPI and PRO virtual (webcast only) public meetings will be asked to provide feedback. We expect members of the medical device industry, patient organizations, research organizations, health care professionals, and payers to join us for the virtual (webcast only) meeting.

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

   September 29, 2020 – October 31, 2020

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

   At the virtual (webcast only) public meetings, we will request that attendees take our Feedback survey via the free CrowdCompass AttendeeHub app (CrowdCompass by Cvent). Additionally, we will send an email to attendees after the virtual (webcast only) meeting requesting their feedback. Attendees may respond to the survey via the app or email reply.

6. **Confidentiality of Respondents:**

   Using the statement below, we will inform respondents that their participation is completely voluntary and that their responses will be kept private.

"Your participation/non-participation is completely voluntary and your responses will not have an effect on your eligibility for receipt of any FDA services. All respondent identification and information will be anonymous unless otherwise indicated. In instances where respondent identity is needed (e.g., for follow-up of non-respondents), this information collection fully complies with all aspects of the Privacy Act, and data will be kept secure to the fullest extent allowed by law."

7. **Amount and justification for any proposed incentive**

No incentive proposed.

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

We will not be collecting data that is of a sensitive nature.

9. **Description of Statistical Methods**

This survey collects qualitative information. We will use standard descriptive statistics (e.g., measures of distribution and central tendency, dispersion, etc.) when appropriate. For non-numerical feedback, we will cluster ideas by topic.

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

Type/Category of Respondent	No. of Respondents	Participation Time (minutes)	Burden (hours)
Public Meeting Attendee	200	10 minutes	34

REQUESTED APPROVAL DATE: August, 2020

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