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: Pediatric Device Consortia Grant Innovator Feedback Survey

DESCRIPTION OF THIS SPECIFIC COLLECTION

1. **Statement of need:**

   The Food and Drug Administration (FDA)'s Office of Orphan Products Development, Pediatric Device Consortia Grant Program, is conducting a survey of innovators who received assistance from the consortia funded by this grant.

2. **Intended use of information:**

   The survey is intended to get qualitative feedback from innovators who have been assisted by the consortia, as part of the mid-cycle review for the program to assess for applicants' qualification to continue receiving funding.

3. **Description of respondents:**

   Respondents will include innovators who have been assisted by the program—this may include academicians, clinicians, engineers, and business people.

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

   October 1, 2015 through February 15, 2016

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

   Participation in the survey will be completely voluntary. Users may click on a link to initiate the survey from the PDC website. An online survey software, SurveyMonkey, will be utilized to collect the data.

6. **Confidentiality of Respondents:**

   Your participation / nonparticipation is completely voluntary and your responses will not have an effect on your eligibility for receipt of any FDA services. 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 private to the fullest extent allowed by law.

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

   No remuneration will be provided to survey respondents.

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

Survey respondents may voluntarily provide their name, email address, and phone number at the end of the survey if they would like FDA to follow-up on the responses.

9. **Description of Statistical Methods**

On a weekly basis, survey data is compiled and analyzed from Survey Monkey. Data includes the number of survey respondents by consortium, and levels of satisfaction across various dimensions.

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)
Innovators	250	20	83

REQUESTED APPROVAL DATE: July 8, 2015

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