FDA DOCUMENTATION FOR THE GENERIC CLEARANCE OF CUSTOMER SATISFACTION SURVEYS GROUPS (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: Premarket Industry Perception Survey 2011

DESCRIPTION OF THIS SPECIFIC COLLECTION

1. Statement of need:

This survey will capture general opinions of how medical device firms perceive our regulatory and customer service standards. The results will be used internally to identify broad areas of strengths and areas needing improvement during the Medical Device User Fee re-negotiations that is currently under progress. In addition, respondents have the opportunity to offer suggestions for improvement in the premarket review process. In no other forum does CDRH receive application-specific feedback from medical device firms who have recently dealt with CDRH regarding the premarket review process. Generally, FDA only receives formal complaints through the Ombudsman and this survey provides an opportunity to receive both positive and negative feedback on the job scientific reviewers are doing. Since we have methods in place to identify duplicate medical device firms within our potential sample, we are able to avoid duplication and over burdening industry.

2. Intended use of information:

This will be used for internal purposes. The survey results will help Office management gauge how well staff provides services in the pre-market review process and identify areas to improve.

3. Description of respondents:

The respondents are the regulatory affairs medical device contacts from medical device firms that have submitted a device premarket application to the center.

4. Date(s) to be Conducted:

The survey will be conducted over a 3 month period during 2011

5. How the Information is being collected:

The survey will be conducted via telephone calls. In addition, it may be necessary to distribute reminders through email in order to maximize the response rate.

6. Confidentiality of Respondents:

The respondents identifiers will be kept confidential and all results will be aggregated no lower than at the Office Division Levels.

7. Amount and justification for any proposed incentive

The survey is voluntary and no incentives are provided

8. Questions of a Sensitive Nature

This does not apply

9. **Description of Statistical Methods**

A systematic random sample of respondents will be chosen from a list of approximately 5,000 medical device firms receiving premarket application final decisions within the most recent 12 month period. We expect at least a 65% response rate from a sample of about 1,600. If it is not possible to contact a participant or if they do not want to participate, we will choose an alternate application using the same method of extraction for replacement.

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)**
Device Firm (Sponsor) Contact	1,600	8	213

REQUESTED APPROVAL DATE: June 10, 2011

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