

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:

Advisory Committee and Panel Meeting Two-way Communication

DESCRIPTION OF THIS SPECIFIC COLLECTION

1. Statement of need:

The Food and Drug Administration (FDA), Office of Planning, Office of the Commissioner, is seeking OMB approval under the generic clearance 0910-0360 to conduct a survey on communication at FDA Advisory Committee meetings. The purpose of the survey is to assess the ability of Advisory Committee meetings to effectively facilitate two-way communication in order to help identify potential improvements to the Advisory Committee program at FDA. No FDA studies have assessed public perspective on communication at Advisory Committee meetings in the past.

FDA's Strategic Plan for Risk Communication charges the Risk Communication Staff in the Office of Planning to regularly assess whether Advisory Committee meetings effectively facilitate two-way communication. This is defined as dialogue through which information flows both from FDA to the public and from the public to the FDA. In order to fully assess the communication that the public receives, FDA must be able to ask the public about their satisfaction with the communication that currently occurs at Advisory Committee meetings. Without input from the public, FDA will not be able to fully assess two-way communication at Advisory Committee meetings.

2. Intended use of information:

Information will be used to improve the Advisory Committee program at FDA by enhancing the mechanisms through which Advisory Committee and panel meetings facilitate two-way communication between FDA and the public. The survey may be administered on an ongoing basis at future Advisory Committee and panel meetings. Due to limitations with the convenience sample, analyses will be done in the context of understanding that the survey data do not represent population parameters. The data will not be used for the purposes of making policy or regulatory decisions.

3. Description of respondents:

Respondents are attendees of Advisory Committee or Panel meetings. They may be representatives of industry, members of advocacy or patient groups, interested members of the public, press representatives or others.

4. Date(s) to be Conducted: At 6 Advisory Committee/Panel meetings:

August 11-12, 2011

August 15-16, 2011

August 19, 2011

September 12, 2011

September 14-15, 2011

September 20-21, 2011

5. How the Information is Being Collected:

Initially, paper copies of the survey will be placed on chairs in the public seating section prior to the start of selected Advisory Committee meetings. Respondents will be asked to return completed surveys to a designated box at the registration desk upon their departure from the meeting. In the future, electronic versions of the survey can be emailed to meeting attendees who provide their email address upon registering for the meeting. Regardless of the method of dissemination, the survey will clearly be indicated as voluntary.

6. Confidentiality of Respondents:

Respondents are assured that all respondent identification and information are anonymous and kept private to the extent permitted by law.

7. Amount and justification for any proposed incentive

None

8. Questions of a Sensitive Nature

None

9. Description of Statistical Methods

Basic descriptive statistics (distribution, median) of aggregated responses.

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)
Meeting Attendees	Approximately 150 (25 per meeting)	10/60	25

REQUESTED APPROVAL DATE: July 28, 2011

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