# 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:** Interviews with Applicants and Other External Stakeholders Regarding Clarity, Understandability, and Usefulness of FDA's Benefit-Risk Framework (BRF)

## DESCRIPTION OF THIS SPECIFIC COLLECTION

1. **Statement of need:**

   FDA's Center for Drug Evaluation and Research (CDER) will collect qualitative data on the Benefit-Risk Framework that is used to communicate regulatory decisions about New Molecular Entity (NME) New Drug Applications (NDAs) and original Biologic License Applications (BLAs). For each application, the Framework provides a structure for documenting considerations related to a drug's (1) therapeutic area (analysis of the condition and the current treatment options) and (2) product-specific benefits and risks, as well as any potential risk management activities. The purpose of the Framework is to convey this information in a succinct standard format to help both internal and external stakeholders better understand the evidence and reasoning that supported FDA's regulatory decision on the application.

   Two target audiences are applicants and other external stakeholders (e.g., patient groups, healthcare providers, academics). A key objective of the Benefit-Risk Framework with respect to applicants and other external stakeholders is to provide a clear understanding of the reasoning behind FDA's regulatory decision on an NME NDA or original BLA.

   In March 2015, CDER began a staged rollout of revised review document templates to include the Benefit-Risk Framework, starting with the review of NME NDAs and original BLAs. To support this implementation, CDER is performing a qualitative assessment of the clarity, understandability, and usefulness of Frameworks prepared for NME NDAs and original BLAs received between March 1, 2015 and February 28, 2016 (an estimated 45 applications). As part of this assessment, FDA is seeking input from applicants and other external stakeholders on the clarity, understandability, and usefulness of these Frameworks and ways the Benefit-Risk Framework template can be improved to better meet applicant and other external stakeholder needs.

2. **Intended use of information:**

   The data collected under this set of interviews will assist FDA in improving implementation of the Benefit-Risk Framework moving forward. Specifically, understanding the extent to which the initial set of Frameworks developed by FDA were clear, understandable, and useful to applicants and other external stakeholders will assist FDA in modifying the Framework to meet the needs of these audiences. This data collection is also part of a larger project that involves detailed review of Framework documents created by FDA staff and in-depth interviews with FDA staff on implementation of the Framework. Information collected from applicants and other

external stakeholders will complement internal perspectives on the Framework to provide a broad assessment of the Framework's initial implementation.

3. **Description of respondents:**

There are two main respondent groups: (1) applicants whose NME NDAs or original BLAs received between March 1, 2015 and February 28, 2016 received a first-cycle action by May 31, 2017 and (2) non-applicant external stakeholders who might use the information in the Benefit-Risk Framework.

FDA expects that about 45 NME NDAs and original BLAs will be received between March 1, 2015 and February 28, 2016 and receive a first-cycle action by May 31, 2017. FDA's contractor for this work, Eastern Research Group, Inc. (ERG), will perform interviews with applicants for those applications that receive a first-cycle action of approval. ERG will also interview applicants who receive a Complete Response (CR) letter[1] if they receive a Benefit-Risk Framework with the CR letter. Applicant interviews will include 1-3 representatives from applicant teams responsible for these applications (total number of interviewees ≤ 135). In scheduling interviews, ERG will request to interview individuals most likely to review or have a need for the information in the Benefit-Risk Framework (e.g., Directors of Regulatory Affairs, Chief Executive Officers for smaller companies).

For other external stakeholders, FDA has asked its' contractor to interview three types of stakeholders: (1) patient groups, (2) healthcare providers, and (3) academics in relevant fields. These groups will be further grouped by therapeutic area (e.g., oncology, infectious disease, endocrinology, allergy/immunology) or sector within a therapeutic area where appropriate. External stakeholder interviews will include 1-5 representatives from a given stakeholder group for a given therapeutic area or sector: 70 groups in total (total number of interviewees ≤ 350). In scheduling interviews, ERG will request to interview individuals most likely to review or have a need for the information in the Benefit-Risk Framework.

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

FDA will collect this information between January 2016 and July 2017. Interviews will begin upon issuance of first-cycle actions for in-scope NME NDAs and original BLAs. The end point of the collection corresponds to a date for incorporating data from the interviews into a final report for the project.

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

FDA will collect this information through a series of group interviews. FDA has contracted with ERG, an independent consulting firm, to perform these interviews. Most interviews will be teleconferences; ERG may offer the option of face-to-face interviews for groups located near FDA's White Oak campus. Interviews are expected to last 60-90 minutes each. Scripts for the interviews have been attached.

[1] A CR letter is an action by FDA indicating to the applicant that the review cycle has been completed, but that FDA determined the application was not ready for approval. The CR letter allows for the possibility of resubmission of the application at a later date.

6. **Confidentiality of Respondents:**

As noted above, FDA has contracted with ERG to perform these interviews; FDA staff will not participate in any interviews. ERG will handle the processing of data and information from these interviews and will not provide FDA with raw notes from the interviews that contain information on who participated in the interviews. Furthermore, ERG will not associate information provided by applicants or external stakeholders with a specific interviewee.

FDA will know what applicant entities are within scope for these interviews because by definition they have submitted applications to the Agency; FDA will not know which applicant entities accepted or declined interviews or which individuals within the applicant entities participated in interviews. FDA may suggest other external stakeholder groups for the contractor to interview, but will not know exactly what groups (or individuals within groups) are interviewed. In addition, FDA will receive updates from the contractor on the status of interviews (number scheduled, number conducted, common themes at aggregate level), but in no case will such updates include identifying information about interviewees. FDA fully recognizes that applicants and other external stakeholders have the right to refuse to participate in interviews.

The interview scripts will include the following text:

"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 incentive is being offered.

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

No questions of sensitive nature are being asked.

9. **Description of Statistical Methods**

No statistical methods are being used.

***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) |
|---|---|---|---|
| Applicants | 135 (= 3 interviewees per applicant x an estimated 45 | 90 (max) | 203 |

| | | | |
|---|---|---|---|
| | applicants) | | |
| Non-applicant external stakeholders | 350 (= 5 interviewees per group x 70 groups) | 90 (max) | 525 |
| **TOTALS** | **485** | **-** | **728** |

**REQUESTED APPROVAL DATE:** January 2, 2016

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