Part B: Collections of Information Employing Statistical Methods

1. **Describe (including a numerical estimate) the potential respondent universe and any sampling or other respondent selection method to be used. Data on the number of entities (e.g. establishments, State and local governmental units, households, or persons) in the universe and the corresponding sample are to be provided in tabular form. The tabulation must also include expected response rates for the collection as a whole. If the collection has been conducted before, provide the actual response rate achieved.**

   Population and Sample Size

   The population of potential interviewees consists of applicants who receive a first-review cycle action (whether that action represents an approval or not) by September 30, 2016 under FDA's Program for Enhanced Review Transparency and Communication for NME NDAs and Original BLAs in PDUFA V. The number of applications that receive FDA actions varies somewhat from year to year; for the purpose of this estimate of population size, we use a high-end estimated average of 45 such applications per year. The independent contractor conducting the study will interview one to three sponsor representatives per application, bringing the total estimated population size to 135 per year or 540 over 4 years.

   The expected response rate for this information collection is 90%.

Estimated Average Number of Applications Receiving a First-Review Cycle Action Under The Program	Number of Interviewees Per Application	Size of potential respondent universe	Expected Response Rate	Estimated Number of Respondents
45 per year	1-3	135 per year	90%	122
180 over 4 years	1-3	540 over 4 years	90%	486

   Selection Methods

   The independent contractor conducting this information collection will offer interviews to all applicants who receive a first-review cycle action under the Program by September 30, 2016. There will be no sampling or other selection methods.

   Response Rate

   This information collection reflects an agreement negotiated between FDA and industry during the development of PDUFA V and is documented in FDA's Commitment Letter for PDUFA V (http://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM270412.pdf). Program applicants therefore expect these interviews to take place. Industry representatives continue to support this information collection as it is a key aspect of the Program that could inform further enhancements to FDA-industry interactions. This support is evidenced by submitted comments in response to the 30-day notice for this information collection request). We therefore expect that applicants will be motivated to participate in this information collection regardless of outcome

(approval or not) or other application/applicant characteristics. Because members of the potential respondent universe are highly engaged and motivated, we expect a high response rate: 90%.

2. Describe the procedures for the collection, including: the statistical methodology for stratification and sample selection; the estimation procedure; the degree of accuracy needed for the purpose described in the justification; any unusual problems requiring specialized sampling procedures; and any use of periodic (less frequent than annual) data collection cycles to reduce burden.

Statistical Method for Stratification, Accuracy, and Sample Selection

This information collection will encompass the full universe of potential respondents; no statistical methods for stratification, accuracy, and sample selection are required.

Estimation Procedure

None are required.

Unusual Problems Requiring Specialized Sampling Procedures

None are required.

Use of Periodic (Less Than Annual) Data Collection

This request is for a one-time data collection spanning 4 years of the Program as described above.

3. Describe the methods used to maximize response rates and to deal with nonresponse. The accuracy and reliability of the information collected must be shown to be adequate for the intended uses. For collections based on sampling, a special justification must be provided if they will not yield "reliable" data that can be generalized to the universe studied.

Despite the expectation of a high response rate, FDA and the independent contractor will follow good interview practices, including the following:

- In all action letters under the Program, FDA will include a notification about the opportunity to participate in a post-action interview and indicate that the independent contractor will contact the sponsor to that end.
- The independent contractor will send an email to the primary contact person for the application requesting participation in the interview and explaining the importance of the information collection; ERG will offer to conduct the interview at a location (in person or by phone) and date/time that is convenient for the sponsor.
- For those not responding to the initial email (described in the bullet above), ERG will send follow-up emails and place follow-up telephone calls as needed to ensure that the appropriate person in the sponsor company receives the interview invitation; ERG will discuss logistical options as needed to optimize the convenience of the interview for interviewees.
- ERG will send an appointment invitation and reminders (with all contact and logistical information needed) to every interviewee.

The independent contractor will track non-responses to gauge potential non-response bias. As explained above, however, response rates are expected to be high regardless of application action and characteristics.

4. **Describe any tests of procedures or methods to be undertaken. Tests are encouraged as effective means to refine collections, but if ten or more test respondents are involved OMB must give prior approval.**

   In developing the interview protocol and instrument, the independent contractor consulted experts to refine procedures and methods as much as possible. In addition, ERG will use the first five interviews as an opportunity to assess interview procedures and refine operational procedures if necessary.

5. **Provide the name and telephone number of individuals consulted on the statistical aspects of the design, and the name of the agency unit, contractor(s), grantee(s), or other person(s) who will actually collect and/or analyze the information for the agency.**

   FDA contracted with Eastern Research Group, Inc. (ERG) of Lexington, MA to design the interview protocol and instrument, implement the interviews, and analyze the resulting information collected. The information collection design team included the following individuals:

   - Valerie Overton (781) 674-7398; valerie.overton@erg.com
   - Dr. Lou Nadeau (781) 674-7316; lou.nadeau@erg.com
   - Patrick Zhou (301) 796-2107; patrick.zhou@erg.com