United States Food and Drug Administration

Generic Clearance for the Collection of Qualitative Feedback on FDA Service Delivery

OMB Control No. 0910-0697

SUPPORTING STATEMENT

Part B. Statistical Methods

Data collection methods and procedures will vary. However, the primary purpose of these collections will be for internal management purposes. There are no plans to publish or otherwise release this information.

1. Respondent Universe and Sampling Methods

   The activities under this clearance may involve identifying samples of self-selected customers, as well as using convenience and quota samples, with respondents selected either to cover a broad range of customers or to include specific characteristics related to certain products or services. Results will not be used to make statements representative of any universe of individuals, to produce statistical descriptions (careful, repeatable measurements), or to generalize the data beyond the scope of the sample. The specific sample planned for each individual collection and the method for soliciting participation will be described fully in each collection request.

   Qualitative surveys are tools used by program managers to change or improve programs, products, or services. The accuracy, reliability, and applicability of the results of these surveys are adequate for their purpose.

   The samples associated with this collection are not subjected to the same scrutiny as scientifically drawn samples where estimates are published or otherwise released to the public.

2. Procedures for the Collection Information

   Data collection methods and procedures will vary and the specifics of these will be provided with each collection request. FDA expects to use a variety of methodologies for these collections. For example, FDA or its contractors may use commercial survey-specific software to automate its collection and analysis of feedback. In addition to physical copies, information collection instruments may be electronically disseminated and/or posted on target pages of FDA's Web site. We may also use telephone scripts, personal interviews, and focus groups with professional guidance and moderation.

3. Methods to Maximize Response Rates and Deal with Non-response

   Information collected under this generic clearance will not yield generalizable quantitative findings; it can provide useful customer input, but it does not yield data about customer opinions that can be generalized to the larger population.

4. Test of Procedures or Methods to be Undertaken

   Pretesting may be done with internal staff members, a limited number of external colleagues, and customers who are familiar with the programs and products. If the number of pretest respondents exceeds nine members of the public, FDA will submit the pretest instruments for review under this generic clearance.

5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

   As appropriate, each program will consult with FDA statisticians or outside contractors in developing, designing, conducting, and analyzing customer service surveys. FDA will include the names and contact information of persons consulted in the specific information collection requests submitted under this generic clearance.