

United States Food and Drug Administration

FDA Rapid Response Surveys  
(Generic Clearance)

OMB Control No. 0910-0500

SUPPORTING STATEMENT

**Part B. Statistical Methods**

1. Respondent Universe and Sampling Methods

FDA will identify the respondent universe for each Rapid Response Survey. The appropriate respondent (i.e., typically risk managers, but occasionally nurses or physicians) for each survey will be determined by the medical product issue and the surveillance questions to be answered. However, to provide some general understanding of the size of potential universe samples, please see the example below:

Number of risk managers belonging to the American Society for Healthcare Risk Management is approximately 5,000.

Number of hospitals is approximately 6,100.

FDA has available lists of professional organizations and medical institutions. These lists are kept up to date and used when the agency is sending out Safety Alerts and Public Health Advisories. These lists are one source of identifying potential respondents for these FDA Rapid Response Surveys. In the past, FDA also has excellent working relationships with professional organizations, such as the American Society for Healthcare Risk Management, that have offered to assist us in identifying respondents for these data collection efforts.

Additionally, FDA has developed a sentinel-based system (MedSun) to represent the various types of user facilities in the United States. Risk managers at different groups (hospitals, nursing homes, etc.) of these sentinel sites would function as the sample when appropriate and would be contacted electronically.

FDA proposes to draw a purposeful sample of respondents for each survey. Since the survey data will not be used for estimates of incidence, there is no need for a probability sample, and in fact, the selection of a probability sample would significantly delay the data collection effort and increase the likelihood of more injuries occurring before FDA could take action.

Over the years, FDA has developed more and more relationships with health professional organizations. These organizations are willing to send FDA surveys out to their membership via list-serves. This makes reaching numerous respondents very easy.

A 70% response rate is expected. The impact of a lower response rate to any given questionnaire will be considered before FDA acts to improve the response rate. FDA may determine that action is required based solely on only information from a few sources. The individuals analyzing the responses are clinical experts in the medical product under investigation. Therefore, if the response rate to a particular survey is low, but a problem pattern is noted in the obtained responses, FDA will act immediately without additional non-response follow-up. The goal of the information collection program--i.e., to obtain data to perform a risk analysis and to provide the public with important information about possible hazards with medical products as soon as FDA becomes aware that such hazards exist--could be met without additional follow-up.

In other situations, a high non-response rate might prohibit FDA from determining whether a public health hazard exists. In these situations, FDA will conduct a follow-up electronically or by telephone (please see #3, below for details).

The results are not intended to yield results that are statistically projectable, nationally representative, or precise estimates of population parameters.

## 2. Procedures for the Collection of Information

Once FDA identifies the need for additional surveillance data to address a potential public health hazard, the appropriate respondents will be identified either through FDA's lists or through the appropriate professional organizations.

As described in #1, above, there is a need to require specialized sampling procedures. The reasons for purposeful sampling include:

- the need to obtain targeted information from facilities or professionals which have the most experience in the use of certain medical products;
- the data will not be used for estimates of incidents, so a probability sample is not required, and may even be deleterious to the timeliness of the process;
- the proposed data collection is qualitative, not quantitative; and,
- the limited resources available at FDA.

FDA, therefore, proposes to draw a purposeful sample of respondents for each survey and the number of respondents will be selected based on the information needed, the type and availability of the appropriate respondent, and the potential seriousness of the issue.

FDA or its representatives will contact respondent facilities and health care professionals electronically, whenever possible, or, rarely, by telephone.

When the surveys are returned, all facility identifiers will be removed. The surveys will be processed, and the data sent to the analysis team.

Results will be characterized primarily using descriptive statistics since FDA generally lacks sufficient denominator information to do more sophisticated analysis. Again, the

information collection is to obtain qualitative data not quantitative data. The data collected will be used to determine the risk to patient safety and to aid in developing appropriate FDA actions.

Degree of accuracy needed. The purpose of the rapid response surveys is to collect information in an expeditious manner, which will help FDA to better understand a particular medical product problem to determine whether a public health issue is emerging. Whenever FDA has contacted health professionals who reported an adverse medical product event for more information, the individuals have been diligent in responding to FDA's questions and accuracy has not been a problem. Therefore, we fully anticipate that the health professionals contacted for each survey will respond with information that is as accurate as possible at the time of receiving the survey questions.

If the need arises to perform long-term evaluations of a particular problem, FDA will provide research agendas to obtain more analytical information and will submit the proper request for a collection of information request to OMB as needed.

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

To encourage maximum response rates, FDA will ensure respondents that any identifiers on response forms will be destroyed before giving the data to the analysis team.

In situations where a high non-response rate might prohibit FDA from determining whether a public health hazard exists, FDA will conduct a follow-up.

If the second communication does not obtain increased participation, FDA will contact the professional association(s) representing the respondents and request that the association aid in the collection of the information. Respondents may be more comfortable sending the responses to their association rather than to a regulatory agency.

### 4. Test of Procedures or Methods to be Undertaken

Scientists at FDA routinely contact the reporting facility to obtain additional information. While this might answer specific questions related to a specific report, it is limited in scope. Often, we need information from additional facilities. This information will be obtained through use of the FDA Rapid Response Surveys. Further, we had presented the methodology described in this proposal to the association cited earlier (representative for risk managers) to obtain its input. The association agreed that the voluntary, anonymous approach described is the best means to obtain critical information in a timely manner.

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

Depending on the issues under evaluation, to analyze the data the analysis teams will be set up in the centers that will use this Rapid Response Survey mechanism.