FDA Rapid Response Surveys
(Generic Clearance)

0910-0500

SUPPORTING STATEMENT

B. Statistical Methods (used for collection of information employing 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 3,600.

Number of hospitals is approximately 6,000.

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. FDA also has excellent working relationships with professional organizations that have offered to assist us in identifying respondents for these data collection efforts. The American Society for Health and Risk Management is such an example.

Additionally, as noted earlier, FDA has developed a "sentinel" 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 takes action 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 do follow-up electronically or by phone (please see #3, below for details).

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. FDA's MedSun group will also be used as respondents.

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. The number of respondents will not exceed 10,000 per survey.

FDA will contact the facilities and health care professionals electronically, whenever possible, or, rarely, by phone.

Respondents will be asked to send in responses 30 days from the date of initiation of the survey. In the rare occasion when FDA requires immediate information, respondents will be asked to respond in a shorter time frame.

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 emergency 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 come forward with 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

Every effort will be made to maximize response rates. In discussions with the American Society for Healthcare Risk Management, it was clear that respondents must feel confident there is no identifying information on the response forms, including any link to match the form with the name of an institution or individual on the sample list. Thus, to encourage maximum response rates, FDA will destroy any identifiers on response forms 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 do follow-up electronically, or by phone. Three days after the requested date of response, FDA will issue a second communication to all respondents and will delineate further the need for those who have not responded to do so. All respondents must be contacted with this second communication since FDA will not know who has, and has not, already responded.

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

Prior to the first Justification sent to OMB several years ago, FDA had utilized this method of data collection for many years, on a much smaller scale. The scientists at FDA routinely contact the reporting facility to obtain additional information. While this answers 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.

This Rapid Response procedure has now been tested for several years under OMB clearance and works very well. We have never received a complaint from any respondent.

The Consumer Product Safety Commission utilizes a survey method almost identical to the one described in this proposal with highly successful results.

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 are proposing to use this Rapid Response Survey mechanism.