Part B – Supporting Statement – 0910-0341

B. Collection of Information Employing Statistical Methods

1. Respondent Universe and Sampling Methods, and
2. Procedures for the Collection of Information

The organizations and individuals to whom PHNs are directed depend upon the subject of the PHN. Thus, the population of interest is variable and the PHN is sent electronically.

Sample size will be determined by the number of volunteer respondents. In the case of the questionnaire survey proposed, the desired precision can be expressed as being confident that, in 95 out of 100 cases where the sample is drawn in the same manner as was the current sample, the obtained response in a replicative survey (e.g., a percentage of the sample asserting a particular perception about a PHN) would be within the range of 10 percentage points above or below (i.e., +- 10%) the response (the percentage) obtained in the present survey.

Following completion of data collection, frequencies and percent distributions will be calculated for questionnaire items, and open-ended items will be categorized by content. The following estimates will be calculated using standard descriptive measures such as frequency tables and cross-tabulations:

1. Estimate of prevalence of use of PHN information by health care providers

2. Estimate of various actions taken by health care providers as a result of information contained in PHNs

3. Evaluation of respondent suggestions for improving the format of the PHN or process

3. Methods to Maximize Response Rates and Deal with Nonresponse

Explaining the importance of the study and value to the respondent is designed to maximize response rates. Since the survey will be conducted electronically on a volunteer basis, there is no plan for dealing with nonresponse.

4. Test of Procedures or Methods to be Undertaken

The proposed questionnaire was shown to several personnel in two national health care organizations, along with FDA staff knowledgeable in areas of survey design, questionnaire development, and writing/editing. All of these inputs contributed to the phrasing, format and topical items included in the final version of the questionnaire.

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

The data will be collected and analyzed by the FDA. When this survey was originally proposed, employees in CDRH's Office of Surveillance and Biometrics were consulted with regard to statistical methods. CDRH/OSB will collect the surveys and arrange for analysis.