

**SUPPORTING STATEMENT FOR
FDA SAFETY ALERT/PUBLIC HEALTH ADVISORY READERSHIP SURVEY
OMB NUMBER 0910-0341**

A. Justification

1. Circumstances Making the Collection of Information Necessary

The Food and Drug Administration (FDA) is the regulatory Agency responsible for the safety and effectiveness of a variety of health products including medical devices and radiological products. Specifically, the Center for Devices and Radiological Health (CDRH) carries out FDA's regulatory mandates regarding medical devices and radiological products. To ensure public health, CDRH must be able to effectively communicate risk to health care practitioners when there is a real or suspected threat to the Public's health. CDRH has two main notices for transmitting information concerning these risks to user communities: the safety alert (SA) and the public health advisory (PHA). Through a process for identifying and addressing postmarket safety issues related to regulated products, CDRH determines when to publish and mail safety alerts and public health advisories. FDA has statutory authority for communicating these risks. Section 705 (b) of the Federal Food, Drug, and Cosmetic Act spells out FDA's authority to disseminate information concerning suspected or imminent danger to public health by any regulated product.

This is a request for approval to conduct a survey to determine the impact of the safety alert and public health advisory on the behavior and knowledge of the recipients. The collection of this data is an important step in determining how well CDRH is communicating risk. Therefore, this study seeks to determine how well the SA and PHA notices meet their goals and how to improve their value as a means of risk communication.

CDRH continues to assess whether the SA or PHA contributes a beneficial outcome by modifying the recipient's knowledge or behavior. The results from this survey will emphasize the quality of the notices and customer satisfaction. This will enable CDRH to better serve the public by improving the effectiveness of the alerts and advisories.

2. Purpose and Use of the Information

The Office of Surveillance and Biometrics (OSB) within CDRH is the focal point for processing postmarket safety issues. They conduct an initial evaluation of a potential problem and then determine public health risk. If it is one that OSB feels should be addressed and communicated to relevant health professionals they decide what message should be conveyed. The determination of whether a safety alert or public health advisory will be issued is based mainly on the risk associated with the device. For instance if the problem and solutions are known and there have been either deaths or serious injuries associated with the device, then OSB generally issues a safety alert. If the problem is not understood and there is only potential for serious injury or death, then OSB issues a public health advisory. The audience outlined in the assessment of the problem determines the addresses.

The data from the survey will be used to help focus CDRH policy for the safety alerts and public health advisories. Understanding how their target audiences view these publications will aid in determining what, if any, changes should be considered in their content, format, and method of dissemination. Printing and labeling costs for FY00 are budgeted at approximately \$30,000. If these data are not collected, FDA will have to make relatively uninformed editorial and budgetary decisions.

The present survey is driven by the objectives listed below:

1. How clearly the problem addressed in the SA/PHA is identified.
2. How easily the problem addressed in the SA/PHA is understood.
3. How clearly actions for reducing risk are explained.
4. How useful and timely the information contained in the SA/PHA is.
5. Whether the reader was aware of the problem prior to receiving the SA/PHA.
6. Whether the reader has taken any action to eliminate or reduce risk as a result of information in the SA/PHA.
7. Whether the recipients are interested in accessing SA/PHAs electronically or by FAX.
8. How the target audience might be expanded.
9. How the FDA SA/PHA program might be improved.

If the information in the SA/PHAs is determined not to be timely, FDA may wish to explore other methods of dissemination such as FAX or the Internet, or the use of professional publications. If the problems addressed in the SA/PHAs are not clearly identified or easily understood, FDA may wish to revise its editorial policies to make these areas more explicit. And if risk-reducing behaviors are not taken as a result of information in the SA/PHAs, alternative methods of communicating risk to consumers can be explored. All of these considerations have important cost consequences, and without an effort at evaluating readership needs, the growing cost burden to FDA of producing alerts and advisories will remain an unresolvable issue.

3. Use of Information Technology and Burden Reduction

Information technology that is available for reducing response burden, such as computer assisted personal or telephone interviews (CAPI/CATI) or electronic submission of responses, is appropriate mainly in larger-scale surveys involving the collection of large amounts of data. These techniques are either irrelevant (i.e. CATI) or are not cost effective for collecting the relatively small amounts of data called for in this survey.

Safety alerts and public health advisories are available through the Internet. CDRH intends in the next year to post summaries of the survey's results to the Internet to facilitate rapid respondent and public access to the data.

4. Efforts to Identify Duplication and Use of Similar Information

The Office of Inspector General (OIG) conducted a study to provide information on the effectiveness of the FDA Urgent Notice on recalled blood glucose test strips. Results indicated that about one-third of pharmacies surveyed did not receive the notice; of those who did, about one-half first learned of the test strip problem through the notice. The proposed survey will collect information on the preferred method for dissemination of safety alerts and advisories. Its focus is broader, however, and will include questions regarding the clarity, timeliness, and usefulness of the alerts and advisories. Unlike the OIG study, it will be conducted on a continuing basis, whenever an alert or advisory is issued.

A literature search was conducted for studies that sought to determine the clarity, timeliness, and usefulness of FDA Safety Alerts and Public Health Advisories. While several studies have been conducted to examine consumers' perceptions of experiences with FDA regulated products, no data have been collected routinely to examine the usefulness of each FDA safety alert and public health advisory issued.

5. Impact on Small Business or Other Small Entities

This collection does not specifically target small businesses. Data will be collected from health care professionals (e.g. hospital and nursing home administrators, biomedical engineers). While some of these respondents may work in small businesses, it is anticipated that filling out the brief proposed questionnaire represents a minimal burden both to the respondent and the business.

6. Consequences of Collecting the Information Less Frequently

Because safety alerts and public health advisories are issued in response to some potentially serious device problems, their publication is intermittent. Forty-six alerts or advisories have been issued between 1983 and the present, an average of about three per year. Data collection will follow each future notice. This is important because the SA/PHAs are issued to different populations, depending on the nature of the device problem. Less frequent information collection would result in loss of feedback on a particular device issue. Subsequent decisions regarding format and content of alerts and advisories would likely be based upon less precise information.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

The plan to conduct the proposed data collection is fully consonant with the guidelines in 5 CFR 1320.5.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

No comments were received in response to the November 26, 1999 *Federal Register* notice (64 FR 66479).

9. Explanation of Any Payment or Gift to Respondents

Respondents will receive no remuneration for their participation in the survey. Given the brevity of the questionnaire and corresponding modest response burden, it is not expected that payment to respondents for their participation would necessarily increase response rate. It would also significantly increase costs to the FDA, since the proposed survey would be conducted whenever an alert or advisory is issued.

10. Assurance of Confidentiality Provided to Respondent

The data from this study will be totally confidential. The universe from which samples are selected generally consists of institutions, such as hospitals and nursing homes. The identifiers on questionnaire mailing labels are titles, not individuals. Thus, a survey would be addressed to a hospital or nursing home administrator rather than to any particular individual. The names of respondents, or any other personally identifying information, will not be requested.

There could be some instances in which an alert or advisory is sent to individual health care professionals, such as physicians or dentists. Although questionnaires will not contain any personally identifying information, they will be coded to permit follow-up mailings; this code will provide an association between the questionnaire and the recipient as identified on the mailing key. This code will be removed from returned questionnaires and destroyed.

11. Justification for Sensitive Questions

None of the survey questions are considered to be sensitive.

12. Estimates of Hour Burden Including Annualized Hourly Costs

Based on the history of the safety alert and public health advisory program, it is estimated that an average of three collections will be conducted a year. The total burden of response time is estimated at 10 minutes per survey. This was derived by CDRH staff completing the survey and through discussions with the contacts in two trade organizations mentioned previously.

Estimated Annual Reporting Burden¹

Number Of Respondents	Annual Frequency Per Respondent	Total Annual Responses	Hours Per Response	Total Hours
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308	3	924	.17	157
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¹There are no operating and maintenance costs nor capital costs associated with this collection of information.

13. Estimate of Other Total Annual Cost Burden to Respondents

There will be no costs incurred by respondents.

14. Annual Cost to the Federal Government

The total FTE estimate cost beyond ordinary mailing of alerts and advisories is 240 hours. This roughly translates into .14 FTEs or \$12,880 (based on 1999 FTE of 1750 hours at \$92,000). These figures represent a total cost to FDA for data entry, analysis, photocopying, and envelope stuffing, for approximately three surveys a year. The rest of the costs are incurred through the regular mailing of the notifications. There are potentially three mailings associated with each survey – the initial mailing and potentially two follow-up mailings. The maximum cost of paper for all three mailings three times a year will be \$125. The maximum cost of preprinted envelopes for all three mailings three times a year will be \$50. The maximum estimate of the postage for all three mailings three times a year will be \$915.

15. Explanation for Program Changes or Adjustments

This is an extension of an information collection program. No new adjustments in burden are necessary because the estimates are the same.

16. Plans for Tabulation and Publication and Project Time Schedule

A summary of each survey’s findings will be issued internally within three months after the data collection has ended. Survey results will be available to the OSB Staff responsible for alerts and advisories so that appropriate policy and format changes may be taken.

Descriptive statistics and frequency responses will be used in the analysis of the survey data. Some cross tabulations may be done across the title of the individual responding to the survey and several questions within the survey. This may show some underlying relationships between position type and attitudes toward the format of alerts and advisories.

The schedule for this survey depends entirely on the number of alerts and advisories mailed. At best these mailings are unpredictable. However, it is planned that within three months of the completion of any data collection, a report of findings will be issued.

All safety alerts and public health advisories are made available on the CDRH website ([HTTP://WWW.FDA.GOV/CDRH/Safety.html](http://www.fda.gov/cdrh/safety.html)). Each safety alert or public health advisory includes a paragraph that states that alerts and advisories are available on the website, and includes the web address. The alerts and advisories also include information on how to subscribe to a listserve, so that future alerts and advisories can be received via email.

17. Reason Display of OMB Expiration Date is Inappropriate

The OMB number and expiration date will be listed on the survey.

18. Exemption to Certification for Paperwork Reduction Act Submissions

No exemptions requested.

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 safety alerts and public health advisories are directed depend upon the subject of the alert or advisory. Thus, the population of interest is variable. A past alert, for example, which dealt with retinal photic injuries from surgical microscopes was sent to about 18,000 ophthalmologists and cataract centers, while another alert on hospital bed entrapment hazards was directed to about 97,000 hospital administrators, nursing homes and directors, home health agencies, hospices, manufacturers and others. The range in size of the population has typically varied from about 18,000 organizations and individuals to about 100,000.

The FDA maintains a user facility database, from which mailing labels for safety alerts and advisories are generated. This database was created from several sources, and records are not in any uniform order. Some are roughly grouped by date, then by state postal code, while others are grouped by facility type, then state. Since questionnaire items address general issues such as clarity, timeliness and usefulness of alerts and advisories, we have no reason to expect variation in responses according to type of notice (alert or advisory) or population sub-groups. A simple random sample will be selected from the user facility database. Should the population of interest not be included in the user facility database, the FDA will obtain the appropriate mailing list from commercial sources and select a simple random sample from it.

Determination of sample size for a simple random sample takes into account the confidence level desired, the percent of respondents in the sample who are expected to respond in a particular way to any specific question, and the precision desired. 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 safety alert or public health advisory) would be within the range of 10 percentage points above or below (i.e., $\pm 10\%$) the response (the percentage) obtained in the present survey. In cases where the universe (the population) is as large as any of those in the proposed investigation, a sample size of 123 is needed for this level of precision, assuming a split of 50/50 between two alternative answers to a question item. (This latter assumption produces the most conservative estimates of sample size.)

Other considerations that need to be factored into the final determination of sample size include non-deliverable survey questionnaires (for example, if the respondent has moved or the organization has closed) and deliberate non-response. These factors strongly support a reasoned increase in sample size. Assuming 60 percent as a reasonable allowance for non-receipt of the survey questionnaire and deliberate non-response, a sampling of 308 will be drawn from the user facility or other appropriate database. This percentage was based on the experience FDA obtained in 1990 from a similar readership survey on the Drug Bulletin. For that survey, the actual non-response was higher than expected. So the 60 percent takes into account a greater non-response rate than what would be expected for this type of survey based on the Drug Bulletin experience (50 percent non-respondents). This was done in order to overcompensate and adequately survey the population to achieve the desired result of 123 respondents.

In the four surveys that have been conducted, under the current approval, in 1998/1999, the return rates have been 59%, 28%, 88%, and 56%. In all of these surveys, except the one with 28% return, the 123 returns needed to provide the precision discussed above, have been received.

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 SA/PHA information by health care providers
2. Estimate of various actions taken by health care providers as a result of information contained in SA/PHAs
3. Proportion of respondents who would prefer alternative methods of distributing SA/PHAs, such as electronic transmission
4. Evaluation of respondent suggestions for improving the format of the SA/PHA form or process

3. **Methods to Maximize Response Rates and Deal with Nonresponse**

Within one week following mailing of a safety alert or public health advisory, each of the selected respondents will be sent a questionnaire by first-class mail, with a copy of the alert or advisory. This will be accompanied by a cover letter from the Director of the Center for Devices and Radiological Health that stresses the importance of each respondent returning a completed questionnaire. Finally, a postage-paid and pre-addressed envelope will be included in the package for returns.

After a two-week period, a second questionnaire with a second version of the cover letter will be sent to all those who did not respond to the first mailing. A coded number that is associated with an organization's name or individual's title will identify these non-respondents. This information will be destroyed immediately following the completion of data collection. After a second two-week period (i.e., four weeks after the initial mailing), a third questionnaire with another letter will be sent to all remaining non-respondents. At this point, no further contact will be attempted with those who have not returned the questionnaire, and all those who do not respond within seven weeks of the first mailing will be considered non-respondents.

The procedures described in this section are all designed to maximize response rates. By including a cover letter from the Director of CDRH, the importance of the study and value to the respondent is stressed. The two follow-ups are seen as essential to the success of the survey effort. A 1972 survey of physician attitudes toward the FDA Drug Bulletin used similar follow-up techniques but contacted a sample of non-responders; the study obtained a 72% response rate. Given the numerous follow-up procedures built into this study, the prestige of the FDA as the sponsoring organization, the importance of the safety alert or advisory, and the brevity of the survey instrument, we anticipate achieving at least a 75% response rate for health care professionals. Therefore, given that only healthcare professionals are surveyed, we expect a 75% response rate for the overall survey.

In the four surveys that have been conducted, under the current approval, in 1998/1999, the return rates have been 59%, 28%, 88%, and 56%. The overall return rate for all four surveys was 55%. In all of these surveys, except the one with 28% return, the 123 returns needed to provide the precision required by the survey design have been received. Considering that the survey design objectives have largely been met, we consider the survey procedures adequate, and wish to maintain those procedures.

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. Both Cathy Backinger, Ph.D., and George Koustenis, (301) 827-4368, in CDRH's Office of Surveillance and Biometrics were consulted with regard to statistical methods. The Issues Management Staff will collect the surveys and arrange for analysis.