SUPPORTING STATEMENT FOR
FDA PUBLIC HEALTH NOTIFICATION READERSHIP SURVEY
FORMELY KNOW AS "FDA Safety Alert/Public Health Advisory Readership Survey"
OMB CONTROL 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. Section 705(b) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 375(b) authorizes FDA to disseminate information concerning imminent danger to public health by any regulated product.
http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/FDCActChapterVIIGeneralAuthority/ucm109393.htm

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 a Public Health Notification (PHN) for transmitting information concerning these risks to user communities. CDRH changed the title of the survey from "FDA Safety Alert/Public Health Advisory Readership Survey" to "FDA PUBLIC HEALTH NOTIFICATION READERSHIP SURVEY" to accurately reflect the information that is being collected. PHNs are released and available to organizations such as hospitals, nursing homes, hospices, home health care agencies, manufacturers, retail pharmacies, and other health care providers. Through a process for identifying and addressing postmarket safety issues related to regulated products, CDRH determines when to release PHNs. FDA has statutory authority for communicating these risks in section 705 (b) of the Federal Food, Drug, and Cosmetic Act, which spells out FDA's authority to disseminate information concerning suspected or imminent danger to public health by any regulated product. Section 1701(a)(4) of the Public Health Service Act (42 U.S.C. 300u(a)(4) also authorizes FDA to conduct research relating to health information. FDA seeks to evaluate the clarity, timeliness, and impact of PHNs by surveying a sample of recipients. http://straylight.law.cornell.edu/uscode/42/300u.html

This is a request for OMB approval to continue to conduct a survey to determine the impact of PHNs 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 PHNs meet their goals and how to improve their value as a means of risk communication.

CDRH continues to assess whether the PHN 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 PHNs.

2. Purpose and Use of the Information

The Office of Surveillance and Biometrics (OSB) within CDRH assists with processing postmarket safety issues by conducting evaluations of a potential problems and then determining 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 releasing a PHN 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 PHN. 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 PHNs. 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. If these data are not collected, FDA will have to make relatively uninformed editorial decisions.

The present survey is driven by the objectives listed below:

1. How clearly the problem addressed in the PHN is identified.

2. How easily the problem addressed in the PHN is understood.

3. How clearly actions for reducing risk are explained.

4. How useful and timely the information contained in the PHN is.

5. Whether the reader was aware of the problem prior to receiving the PHN.

6. Whether the reader has taken any action to eliminate or reduce risk as a result of information in the PHN.

7. How the target audience might be expanded.

8. How the FDA PHN program might be improved.

If the information in PHNs is determined not to be timely, FDA may wish to explore other methods of dissemination such as the use of professional publications. If the problems addressed in the PHNs 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 PHNs, alternative methods of communicating risk to consumers can be explored. All of these considerations have important resource consequences, and without an effort at evaluating readership needs, the growing resource burden to FDA of producing PHNs will remain an unresolvable issue.

3. Use of Information Technology and Burden Reduction

Information technology that is available for reducing response burden, such as electronic submission of responses, is appropriate since our PHNs are available on the Internet. Although we are collecting relatively small amounts of data in this survey, electronic submission of responses is the most appropriate method.

PHNs are available through the Internet. CDRH will 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

Other studies are not collecting information on specific CDRH PHNs. The proposed survey will collect information about PHNs and will include questions regarding the clarity, timeliness, and usefulness of them. It will be conducted on a regular basis as PHNs are released.

A literature search was conducted for studies that sought to determine the clarity, timeliness, and usefulness of FDA Safety Notices. 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 a specific FDA PHN released.

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 responding to the survey represents a minimal burden both to the respondent and the business.

6. Consequences of Collecting the Information Less Frequently

Because PHNs are issued in response to some potentially serious device problems, their publication is intermittent. An average of about eight PHNs is released per year. Data collection will follow future PHNa. This is important because the PHNs are issued for 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 PHNs 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 consistent with the guidelines in 5 CFR 1320.5.

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

The 60-day notice was published on published on August 24, 2009 (74 FR 42674). No comments on the information collection were received.
http://edocket.access.gpo.gov/2009/pdf/E9-20247.pdf

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 on a regular basis as PHNs are 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 questionnaires are titles, not individuals. Thus, a survey would not be taken by any particular individual. The names of respondents, or any other personally identifying information, will not be requested.

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 PHN program, it is estimated that an average of three collections will be conducted a year. The total burden of response time is estimated at 15 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 Burden[1]

FD&C Act	Number Of Respondents	Annual Frequency Per Response	Total Annual Responses	Hours Per Response	Total Hours
Section 705(b)	308	3	924	.17	157

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Annual Cost to Respondents

There will be no costs for respondents.

13. Estimate of Other Total Annual Cost Burden to Respondents

There are no capital costs or operating and maintenance costs associated with this collection of information.

14. Annual Cost to the Federal Government

The total FTE estimate cost for data analysis is 160 hours per year. This roughly translates into .1 FTEs or $10,000 (based on Fiscal Year 2009 FTE of 160 hours at $120,000). Since the

surveys will occur electronically, no mailing costs will be incurred.

15. Explanation for Program Changes or Adjustments

This is a reinstatement without change. No changes in the burden estimate occurred**.**

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 PHNs 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 PHNs.

The schedule for this survey depends entirely on the number of PHNs. At best these 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 PHNs are made available on the FDA website (http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/PublicHealthNotifications/default.htm). The PHNs include information on how to subscribe to a listserve, so that future PHNs 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.