FDA Safety Communication Readership Survey

0910-0341

SUPPORTING STATEMENT

Terms of Clearance: None.

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, patients, caregivers, and consumers when there is a real or suspected threat to the Public's health. CDRH uses Safety Communications to transmit information concerning these risks to user communities. CDRH changed the title of the survey from "FDA PUBLIC HEALTH NOTIFICATION READERSHIP SURVEY" to "FDA Safety Communication Readership Survey" to accurately reflect the information that is being collected. Safety Communications are released and available to organizations such as hospitals, nursing homes, hospices, home health care agencies, manufacturers, retail pharmacies, and other health care providers; as well as patients, caregivers, consumers, and patient advocacy groups. Through a process for identifying and addressing postmarket safety issues related to regulated products, CDRH determines when to release Safety Communications. 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 Safety Communications by surveying a sample of recipients.

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

CDRH continues to assess whether the Safety Communication contributes a beneficial outcome by modifying the recipient's knowledge. The results from this survey will emphasize the quality of the Safety Communications and customer satisfaction. This will enable CDRH to better serve the public by improving the effectiveness of Safety Communications.

This information collection is not related to the American Recovery and Reinvestment Act of 2009 (ARRA).

2. Purpose and Use of the Information Collection

CDRH processes postmarket safety issues by conducting evaluations of a potential problem and then determining public health risk. If it is one that the Office of Communication and Education (OCE) feels should be addressed by communicating to relevant health professionals and patients, they decide what message should be conveyed. The determination of releasing a Safety Communication 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 OCE generally issues a Safety Communication. The audiences outlined in the assessment of the problem help determine the methods of dissemination.

The data from the survey will be used to help focus CDRH policy for Safety Communications. 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 Safety Communication is identified.
2. How easily the problem addressed in the Safety Communication is understood.
3. How clearly actions for reducing risk are explained.
4. How useful and timely the information contained in the Safety Communication is.
5. Whether the reader was aware of the problem prior to receiving the Safety Communication.
6. Whether the reader has taken any action to eliminate or reduce risk as a result of information in the Safety Communication.
7. How the target audience might be expanded.
8. How the FDA Safety Communication program might be improved.

If the information in Safety Communications 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 Safety Communications are not clearly

identified or easily understood, FDA may wish to revise its editorial policies to make these areas more explicit. All of these considerations have important resource consequences, and without an effort at evaluating readership needs, the growing resource burden to FDA of producing Safety Communications will remain an unresolvable issue. Respondents are individuals; private sector for-profit and not-for-profit businesses; State, local, or tribal governments; and Federal Government.

3. Use of Improved Information Technology and Burden Reduction

Information technology that is available for reducing response burden, such as electronic submission of responses, is appropriate since our Safety Communications 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.

Safety Communications 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.

FDA estimates that 100% of the respondents will use electronic means to fulfill the agency's requirement or request.

4. Efforts to Identify Duplication and Use of Similar Information

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

5. Impact on Small Businesses 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. We estimate that no more than 10% of respondents will be small businesses.

6. Consequences of Collecting the Information Less Frequently

Because Safety Communications are issued in response to some potentially serious device problems, their publication is intermittent. An average of about nine Safety Communications is released per year. Data collection will follow future Safety Communications. This is important because the Safety Communications 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 Safety Communications would likely be based upon less precise information.

Respondents will respond to the information collection occasionally. There are no legal obstacles to reduce the burden.

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

There are no special circumstances for this collection of information.

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

In accordance with 5 CFR 1320.8(d), FDA published a 60 day notice for public comment in the FEDERAL REGISTER of 02/10/2014 (79 FR 7677). No comments were received.

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 Safety Communications are issued.

10. Assurance of Confidentiality Provided to Respondents

The data from this study will be kept private to the fullest extent allowed by law. 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

The survey does not include questions of a sensitive nature, such as, sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private.

12. Estimates of Annualized Burden Hours and Costs

12 a. Annualized Hour Burden Estimate

Based on the history of the Safety Communication program, it is estimated that an average of three collections will be conducted per year. The total burden of response time is estimated at 10 minutes per survey. This was derived by CDRH staff completing the survey.

Table 1.--Estimated Annual Reporting Burden					
Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Public Health Notification Readership Survey	300	3	900	0.17	153

12b. Annualized Cost Burden Estimate

There is no cost to respondents.

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

There are no capital, start-up, operating or maintenance costs associated with this information collection.

14. Annualized Cost to the Federal Government

The annual estimate for data analysis is 160 hours per year. Because the surveys occur electronically, no mailing costs will be incurred by the government.

An average full time equivalent (FTE) employee is projected to cost FDA's Center for Devices and Radiological Health (CDRH) $209,632,* which consists of the employee's salary and any overhead which accompanies that employee. Therefore, the average hourly wage rate (including overhead) for an FDA/CDRH employee would be $120, which is the FTE cost, $209,632, divided by 1,750 working hours (rounded).

The burden to government of this information collection is $19,200 per year which is computed by taking the hourly average FTE cost of $120 and multiplying it by 160 hours.

*Based on the FY 2012 President's Budget Request All Purpose Table – Total Program Level table.

15. Explanation for Program Changes or Adjustments

We updated the title of the survey from "FDA PUBLIC HEALTH NOTIFICATION READERSHIP SURVEY" to "FDA Safety Communication Readership Survey" to accurately reflect the information that is being collected.

We updated the estimated number of respondents. This adjustment has caused a reduction of four hours to the total estimated hour burden.

We made several minor changes to the survey questions to adequately reflect Safety Communications that can be targeted to patients, as well as health care practitioners. We do not expect these changes to affect the estimated hours per response or the estimated number of respondents.

- We revised the grammar in questions 1 through 3 to be in second person, rather than third person, so that all the questions are in a parallel format. The respondents are not in the position of answering more broadly than for themselves.
- We added more response options to question 6B, "If yes, how did you first become aware of the problem?" to reflect sources that patients may have used. These

additional response options facilitate OCE's audience analysis to better match our dissemination mechanisms with our target audiences. We also changed question 6 to say "reading" rather than "receiving" because the respondent may access the Web, rather than react to receipt of the Safety Communication.

- We changed the stem of the question and added more response options to question 9. We replaced "My title is" to "I am a" to include medical device industry representatives, students, health educators, patients, caregivers, and patient advocacy group representatives.
- We deleted question 10, as we can adequately glean audience analysis information from question 9.
- We revised the last question, renumbered to 10 from 11, to ask for "suggestions for improving "this FDA Safety Communication" rather than for improving the process. This gives us better access to a wide range of suggestions from the respondent, such as their reaction to content and format.

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 Office of Communication and Education (OCE) Staff responsible for Safety Communications 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 Safety Communications.

The schedule for this survey depends entirely on the number of Safety Communications. 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 Safety Communications are made available on the FDA website (http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/default.htm).

17. Reason(s) Display of OMB Expiration Date is Inappropriate
The OMB number and expiration date will be listed on the survey.
18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.