Survey of "Health Care Providers' Responses to Medical Device Labeling Content

0910-NEW

SUPPORTING STATEMENT PART A

Terms of Clearance: None

A. Justification

1. Circumstances Making the Collection of Information Necessary

The mission of the Food & Drug Administration (FDA), as set out in the Federal Food, Drug and Cosmetic Act (21 U.S.C. 301), is to protect the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products, medical devices, our nation's food supply, dietary supplements, electromagnetic radiation emitting devices, and cosmetics. Through the establishment of a broad base of scientific research and through the promotion of improvements in clinical and health system practices, including the prevention of diseases owing to misuse of medical devices, FDA shall promote health care quality improvement by conducting and supporting research activities.

Currently the general labeling provisions for medical devices under 21 CFR Part 801 Subpart A requires that the name and place of business of the manufacturer, packer or distributor and adequate directions for use be provided. Under 21 CFR Part 801 Subpart D, an exemption for adequate directions for use is provided for prescription medical devices. The exemption requires that certain information "[i]ncluding indications, effects, routes, methods…and any relevant hazards, contraindications, side effects and precautions…" be provided in the labeling. The regulations do not supplant the listing of required information with any additional direction for standardizing what and how the information is to be provided.

FDA has received anecdotal information from Health Care Practitioners (HCPs), health care organizations, device manufacturers, and consumers that suggest that there is widespread interest in the healthcare community in standardized device labeling. The FDA continues to receive medical device adverse event reports of problems that stem from absent labeling, or misinterpretations of the information in labeling. In addition, FDA is concerned that the current lack of standardization in device content and format may interfere with the usefulness of device labeling and heightens the risk of medical error. FDA is also concerned that, based on results from a focus group done earlier this year, HCPs do not have the time or desire to review large documents for instructions for use. These HCPs indicated it would be good to have a shorter reference guide that would help them operate the equipment and also refer them to the longer labeling when needed.

At the present time, there are no regulations in effect that define and describe standard content and format for medical device labeling and instructions for use. In addition, the FDA currently has insufficient information to gauge what information is required to appear in the

labeling for medical devices that is most relevant and important to HCPs to help them operate and use medical devices safely and effectively.

Before FDA promulgated the "physician labeling rule" for human drugs and biologics, FDA conducted focus groups, open public meetings, studies and surveys to inform its regulatory approach. That research supported both the need for standard formatting of drug labeling to enable physicians to locate specific labeling content quickly, and informed the development of a regulation for the content and format of drug and biological product labeling. The format that was ultimately described and promulgated in the regulation was tested by users before it was finalized. The rule for the content and format of labeling for human prescription drug and biological products became effective June 30, 2006.

Building upon the research methodology and success of the approach FDA used to evaluate drug labeling, we propose to ask HCPs to evaluate the quality of a shortened version of labeling (e.g. instructions for use) for a medical device and to report the degree to which they could follow those instructions, how useful the information is, and how well organized the information is. This work will allow FDA to assess whether HCPs find the format and content of device labeling clear, understandable, useful, and user-friendly. Findings will provide evidence to inform FDA's planned regulatory approach to standardizing medical device labeling across the United States. The purpose of this study is to determine the most effective device labeling format for a quick reference guide and inform an FDA's regulatory approach on standardized device labeling. To date, FDA has conducted a series of focus group interviews (under OMB#0910-0497) to obtain qualitative information about whether, how, when, and why HCPs use or don't use medical device labeling; to identify barriers to use of medical labeling, and to identify information users find important and useful. The focus groups were conducted in the spring of 2011. To build on the knowledge obtained in the focus groups and to achieve the goals of this project the following data collections are being proposed:

1. A broad-based survey of 600 HCPs, as outlined in this request, to allow FDA to better understand, from end users' perspectives, the challenges they encounter due to lack of standardization and the associated variation that exists in labeling for medical devices. The HCPs to be surveyed include physicians and other prescribers (20%), nurses (40%), and medical therapists (40%). This distribution reflects the higher usage, as opposed to prescribers, of medical devices by nurses and therapists.
2. A series of 12 to 24 in-depth, face-to-face interviews, also included in this request, are proposed to gather more interactive and comprehensive feedback on various formats for medical device labeling than typically allowed in a survey or focus group. The in-depth interview and the broad-based survey will answer the same research questions and they will complement each other in that the in-depth interview will allow the respondent to give longer and more in-depth responses to the same questions. These data collections will occur concurrently. Because of the different collection modalities and time to complete the survey, the data from the in-depth interviews will not be included in the analysis dataset to be used for obtaining frequencies and examining statistical relationships. Review of adverse events and medical errors has shown that use error (the interaction of the user with the device) is a growing problem. FDA asked health care practitioners in Phase 1 of this contract

how and when they used labeling, understanding that easy and accessible labeling is important to the safe operation of medical devices. Based on the information given to FDA in that study, we formulated a shortened version of labeling which is what is in this survey. We now want to know if it is comprehensive and understandable for the safe operation of medical devices.

This study is being conducted by FDA through the contractor, RTI International, pursuant to FDA's statutory authority to conduct and support research on the safety and efficacy of medical devices.

2. Purpose and Use of the Information Collection

The information will be used by FDA to develop evidence-based guidelines and federal regulations for the content and format (headings, layout, word choices, tables and diagrams) of medical device labeling. FDA is aware that the variety of marketed devices and differences in user populations create challenges to standardizing device labeling. The anticipated final outcome will be standardized medical device labeling that will lead to an increase in the safe and effective use of medical devices, and a reduction in adverse events associated with the use of medical devices. This data collection from the private sector is an important element for the Agency to use in evaluating the existing problems associated with current medical device labeling.

FDA scientific analysts will review the results from this data collection and will combine these results with data gained from the other sources cited above to identify a strategy for developing medical device labeling that will provide information deemed relevant and important to HCPs for the safe and effective use of medical devices and ultimately result in fewer medical errors.

3. Use of Improved Information Technology and Burden Reduction

Data will be collected using an on-line questionnaire (Attachment A). The on-line format will be password protected, minimizing the risk of unwarranted data entry, and maximizing data security. The use of an on-line instrument encourages participants to complete the survey at the time of their choosing.

The use of computerized questionnaire administration will allow us to perform experimental research efficiently and at minimal cost. For example, we will be able to couple the image of the selected sample label with the questionnaire, thereby allowing subjects to answer specific questions and for the research team to compare the responses with the individual label templates.

Approximately two weeks after the mailing of a lead letter requesting that providers go online and complete the survey, a follow up letter will be sent to remind non-respondents about the study. Two weeks after the non-response letter is sent, trained callers will telephone each

potential participant that has not yet responded to see if they received the letter with their log-in information, offer to resend the information, and encourage participation in the survey. Up to seven attempts will be made by telephone to reach the providers and encourage their participation. The callers will use a standardized script to explain the data collection to prospective participants and "gatekeepers" at health care facilities. The callers will work in a centralized location under the supervision of trained managers. The computerized survey and accompanying control system will permit programmed scheduling and will allow callers to update contact information in the event providers would prefer to be contacted at an alternative phone number or receive their log-in information via email. The computerized system will also facilitate programmed release of contact information and mailings. Programmed, or staged, release will enable the contractor to limit the number of surveys in the field at one time thus reducing the likelihood of unneeded mailings and contacts (i.e., over the 600 target number) and increasing the overall higher response rate.

FDA estimates that 100% of respondents will respond to this collection electronically.

4. Efforts to Identify Duplication and Use of Similar Information

A series of literature searches and conversations with other Federal staff working on these issues determined that there are no similar data available. The only other study evaluating medical device labeling was a focus group conducted on a limited scale in 1995. At this time, no other part of the Agency is collecting this type of data related to medical device labeling format and content. Federal agencies and FDA have been engaged in data collection efforts to improve device and drug labeling. However, none of these efforts specifically apply experimental techniques capable of identifying methods for presenting information in the labeling for medical devices.

FDA conducted a focus group in 2011 that was Phase 1 of this project. The objectives were the following:

- Explore current awareness and use of medical device labeling by health care practitioners
- Assess which aspects of device labeling are most important and most likely to be read by health care practitioners
- Explore possible changes to labeling content
- Explore practitioners' satisfaction with current device labeling formatting

Key findings from the focus groups led to the following recommendations:

- Consider creating a shorter device label with the sections seen as most important in addition to keeping the current detailed, longer manual. These sections that are most important include: instructions for use, troubleshooting, warnings, precautions, contraindications, adverse events, manufacturer's contact information, and the lot number or serial number
- Labeling sections that are less important should be kept in a longer version of the labeling since they could still be useful

- -all sections of labeling should be carefully reviewed in light of FDA and regulatory requirements given that some participants were concerned about liability issues
- Device labeling should be designed and written with the needs of the audience in mind, particularly nurses and therapists
- Device labeling should be short, concise, and easy to comprehend quickly
- Consider including only content that will enhance practitioners' understanding of how to properly operate a device or how this device might enhance the quality of a patient's care and minimize risks
- Consider changing the content and format of device labeling including larger font, color, simplicity and more pictures or diagrams to match instructions for use and device contents

5. Impact on Small Businesses or Other Small Entities

This is a one-time survey that will be voluntary for those who choose to participate, and some of these volunteers will be part of a HCP's practice. Given the nature of this survey, we don't believe that there will be an impact on small businesses and other entities.

6. Consequences of Collecting the Information Less Frequently

This is a one-time collection that is based on the results of the first phase of this study finished in the spring of 2011. Without this data collection, FDA will not receive feedback from the HCP community about how it uses device labeling and how FDA might develop effective rules for medical device labeling. Moreover, without this data collection, FDA will not have a quantitative assessment of the possible link between medical device labeling content areas and the risk of improper use of a medical device. FDA is developing a standard content and format for device labeling and must know what the clinical community is thinking in this area in order to develop a standard medical device labeling template that the healthcare community will find useful, and rely upon and ultimately result in safer, more effective use of medical devices. There are no legal obstacles to reduce the burden.

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

This request is consistent with the general information collection guidelines of 5 CFR 1320.5(d)(2). No special circumstances apply. Multiple copies of the form will not be required and this will be a one-time data collection activity.

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 November, 1, 2011(76 FR 67459). Two comments were received, however only one was related to the information collection.

In response to the comments submitted by Advamed, FDA responses are as follows:

(Comment 1) Comment 1 questioned whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility.

(Response) The survey is designed to elicit responses on the formatting, content, and design of the template and not on the specific medical device chosen. This is stated at the beginning of the survey. FDA relies upon knowledgeable researchers to develop appropriate survey tools, and the research methodology to test content, format, and design of labeling is based on their expertise. Drugs instructions are written for all users, including health care providers and patients. The device labeling is written for all users, including health care providers and patients. We agree that industry could provide recommended contents and formats of labeling and encourage industry to do so. This survey is designed for the health care provider and their feedback.

(Comment 2) Comment 2 questioned the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used.

(Response) The survey is designed to elicit responses on the formatting, content, and design of the template and not on the specific medical device chosen. The terms used in the templates such as "warnings", "contraindications", and "brand name" are commonly used terms in labeling for all devices. We are addressing what should be in a shortened version of labeling that will allow the user to operate it safely. The survey was designed by researchers with extensive knowledge in the area of testing labeling. It is anticipated that different health care practitioners will provide different answers based on their experiences; this is why we chose to ask various types of health care practitioners. The objective of the survey is to improve device labeling; it would not be possible to do a survey with a fictitious device that has no intended use as per the suggestion. All devices need to have intended use. Survey research is a widely accepted way of obtaining health information about any topic of interest. This survey will complement information gathered by FDA through focus groups, open meetings with industry, and other stakeholders. The survey has been timed and pretested to assess the time burden required of respondents.

(Comment 3) Comment 3 questioned ways to enhance the quality, utility, and clarity of the information to be collected.

(Response) We did not choose biomedical engineers as part of this survey because we wanted to survey the people who interact with the pump in the presence of patients. The suggestion to add a question about whether a health care professional ever uses or reads device labeling and how to improve access to current device labeling was done in a previous study with focus groups. We developed the template survey based on the responses we received in those focus group sessions. We agree that responses will vary depending on the professional group and anticipate this. We developed this survey with professional researchers who develop surveys, and this was also tested internally. We trust that the questions and how they are asked are what we need in order to inform any further actions on medical device labeling content and format development. In regard to conducting objective usability tests with a range of medical

device types, we encourage others to perform these types of tests and share the results with FDA. Given the large number of medical devices, and the diversity of settings in which they are used, usability testing can be difficult.

The agency has contracted with RTI International who will collaborate with Stephen Woloshin, MD, of Dartmouth University, Lisa Schwartz, MD, also of Dartmouth University, and Maureen Garner, MS, Founder and President of New World Regulatory Solutions, Inc. Drs. Woloshin and Schwartz. They will contribute their knowledge related to issues surrounding drug labeling. Ms. Garner's experience with the medical device industry and issues related to the development and clearance of device labels brings greater depth to the project related to the concerns of device manufacturers

9. Explanation of Any Payment or Gift to Respondents

Participants in the survey will receive a token of appreciation for their participation in the study. We propose providing physicians a $75 incentive, nurse practitioners would be offered $40 and technicians would be offered $25. This amount is appropriate and necessary to gain cooperation from physicians and medical personnel who have demanding work schedules and significant competing demands. Furthermore, physicians are frequently approached to participate in research projects, making them more reluctant to participate. The incentives proposed for the in-depth, face-to-face interviews are $150 for physicians and $100 for nurses and technicians. The higher compensation for the face-to-face interviews accommodates the greater amount of more time required over what would be required by the online survey.

The proposed incentive amounts are consistent with the amounts offered for participation in the focus groups conducted in the first phase of this contract, which were submitted to OMB via generic clearance, OMB Control No.0910-0497 wherein physicians were provided with $150 for participation in a one hour discussion at a focus group facility).

We conducted a short literature review related to incentives and response rates with health care providers. Studies have seen increased response rates in providing monetary incentives to physicians for participation in research studies (Everett, et al. 1997, Kasprzyk, et al. 2001, Malin, et al. 2000). Specific dollar amounts have varied and, unfortunately, most literature on the topic of incentives for healthcare providers is in regards to mail or telephone based studies. No study that directly parallels the methods proposed could be found, however, the work of Dykema et. al., provided the most useful information and most similar methodology to the one proposed.[1] Dykema's study involved a 80-item online survey and 7 follow-ups (3 by US mail, and 4 email). The study specifically tested different incentive amounts, and found that the $100 amount produced the best response rate (25.4%). In addition, Dykema et. al. found that common mail survey techniques such as a small preincetnive had no effect on participation.

The proposed incentives are below amounts paid to physicians participating in the National Survey of Physician Organizations (NSPO3) wherein lead physicians are paid $200. NSPO3 averages 40 minutes to complete and data collection is by phone (i.e., CATI). Response rates

[1] Dykema, J, Steverson, J, et al. (2011). Effects of inentives and prenotification on response rates and costs in a national web survey of physicians. *Evaluation & the Health Professions*, 34(4): 434-447.

among physicians are substantially lower than studies with the general population and incentives significantly improve cooperation (Cull et al., 2005; and VanGeest, et al., 2007;). Incentives also improve survey cooperation among allied health workers (Delnevo, Abatemarco, and Steinberg, 2004). One particular study (Keating et al. 2008) compared response rates to a study of doctors treating patients with lung or colorectal cancer. In this study one group of doctors received an incentive of $20, while the other group received a $50 incentive. The group receiving the higher incentive responded to the survey at a higher rate (67.8% vs. 52.1%). A literature review of studies from 1987-2007 involving physician surveys (Flanigan et. al. 2008) found that, "… physicians viewed no incentive or use of a small incentive as not worth the time to complete the survey. Enclosing too large on [sic] an incentive was viewed as a payment, therefore turning away many physicians. An incentive that was viewed as a 'token of appreciation' had the best result." (p4142)

10. Assurance of Confidentiality Provided to Respondents

Data will be kept private to the fullest extent allowed by law. Information that can directly identify the respondent, including name, business address, email address and telephone number will be collected for the purposes of mailing instruction packets to recruited participants. Participants will be told the purposes for which the information is collected and that any identifiable information about them will not be used or disclosed for any other purpose. Please see Attachments B and C, the draft cover letter and draft telephone script for interviewer.

All materials including the cover letter and questionnaire will be reviewed and approved by RTI's Institutional Review Board (IRB) prior to contacting any sample members. The Office for Human Research Protections (OHRP) has granted a Federal-wide Assurance (FWA #3331 effective until June 17, 2014) to RTI that grants RTI the right to review and approve studies independently. In turn, OHRP has the right to audit RTI's IRB records or any study's procedures at any time to assure that RTI is in compliance with the Federal regulations regarding research with human subjects. Individuals contacted will be further assured of the confidentiality of their replies under 42 U.S.C. 1306, and 20 CFR 401 and 4225 U.S.C.552a (Privacy Act of 1974). In instances where respondent identity is needed, the information collection will fully comply with all respects of the Privacy Act.

The project team will also impose several security measures to ensure protection of confidential information collected from project participants. All computers have Pointsec software installed, are password protected, and access to shared drives is limited to staff who have signed data confidentiality agreements. Any information collected in paper form will be stored in a locked file cabinet and only staff that works with the data will have access to the file cabinet. Any paper-based data will be entered into an electronic database, stored in a password- and write-protected location on the local and/or shared drives, and the paper files will be shredded. Audio recordings will be stored in electronic formats with the protections described above and any tapes will be stored in locked filing cabinets until an electronic copy can be made at which point the tapes will be erased.

The respondents will be de-identified by RTI, the Contractor on this effort, who will be administering the survey. Once the project ends, RTI will destroy all documents that contain the respondents' personally identifying information

11. Justification for Sensitive Questions

There are no questions of a sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

12 a. Annualized Hour Burden Estimate

We expect that the maximum time for reporting burden for any given survey would not exceed 45 minutes, but most respondents will complete in fewer than 30 minutes. Given a sample of a possible 600 respondents to be surveyed, this gives a burden of 300 hours to 450 hours. It is unknown how many of these providers will respond to the on-line questionnaire from FDA, but to provide a conservative estimate of burden, the burden numbers are based on the full complement responding. Similarly, the 24 in-depth interviews will take less than 1 hour to complete, but included in the estimate is the time to obtain consent and provide the incentive for participation.

Table 1.--Estimated Annual Reporting Burden

Data Collection	**Number of Respondents**	**Number of responses per respondent**	Total Annual Responses	Average Burden per Response	**Total hours**
Physicians	120	1	120	0.5	60
Advanced practice nurses (NPs) and registered nurses	240	1	240	0.5	120
Medical technicians	240	1	240	0.5	120
Total Survey	600				300
In Depth Interviews					
Data Collection					
Physicians	6	1	6	1	6
Advanced practice nurses (NPs) and registered nurses	9	1	9	1	9
Medical technicians	9	1	9	1	9
Total In-depth Interviews	24	1	24	1	24
Total Hours					324

12b. Annualized Cost Burden Estimate

Estimated annualized cost burden - Survey

Data Collection	**Number of Respondents**	**Total Burden hours**	**Average Hourly Wage Rate***	**Total Cost Burden**
Physicians	120	0.5	86.03	5162
Advanced practice nurses (NPs) and registered nurses	240	0.5	31.99	3839
Medical technicians	240	0.5	31.60	3792
Total	600	250	40.41	12793

Estimated annualized cost burden – In-depth Interviews

Data Collection	**Number of Respondents**	**Total Burden hours**	**Average Hourly Wage Rate***	**Total Cost Burden**
Physicians	6	1	86.03	516
Advanced practice nurses (NPs) and registered nurses	9	1	31.99	288
Medical technicians	9	1	31.60	284
Total	24	24	40.41	1088

*Hourly wage rate is the weighted average of hourly rates of the types of professionals who will be participating in the survey. Source: "National Compensation Survey: Occupational wages in the United States May 2009," U.S. Department of Labor, Bureau of Labor Statistics.

The total cost burden for this collection is $13,881

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

There are no capital and or operating and maintenance costs associated.

14. Annualized Cost to the Federal Government

Costs for the survey administration and in-depth interviewing include contractor expenses of $349,723 for questionnaire refinement, training interviewers, questionnaire programming, data collection, and analyzing and reporting data. In addition, government staff costs may be incurred for monitoring by the government Project Officer and an assigned team, projected to be about 25% of an FTE's time per year (522 hours). Given an FDA personnel cost of $70 per hour, $36,540 would be spent annually on government staff salaries.

15. Explanation for Program Changes or Adjustments

This is a new collection of information.

16. Plans for Tabulation and Publication and Project Time Schedule

This is a quantitative data collection effort. In order to conduct a rigorous analysis, data analysis will begin immediately upon completion of the data collection. FDA will have a complete edited data set from the survey data, with responses from all open-ended, qualitative questions organized and coded using a taxonomy that will be determined upon completion of the data collection activity. A methodology report, detailing procedures followed in collecting these data, will be prepared. A brief analytical report identifying key findings from the data and a set of recommendations for device label formats and new research questions, with associated methodologies, that can shed further light on issues surrounding device labeling.

In addition, the available data will be saved in a machine readable format (such as Excel, SAS or SPSS) which will allow FDA to generate frequencies and percent's, as well as comparative outputs such as cross-tabulations and regression analyses at will. The resulting data and analysis will provide FDA with findings in order to better inform rule making or legislation that would affect medical device labeling. The report will be available upon request after OMB approval and the survey is finished.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

FDA does not seek this exemption.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.