Survey of Health Care Practitioners for Device Labeling Format and Content

0910-NEW

SUPPORTING STATEMENT

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 require 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 "including indications, effects, routes, methods….and any relevant hazards, contraindications, side effects and precautions…" be provided in the labeling. The regulation does not supplant the listing of required information with any additional direction for standardizing what and how the information is to be provided. 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.

FDA received anecdotal information from health care practitioners (HCPs), health care organizations, device manufacturers, and consumers that suggest there is widespread interest in the healthcare community to standardize device labeling. Research from two previous studies showed that the HCPs want standardized labeling and two public meetings reinforced this as supported by public statements made at these meetings. FDA continues to receive medical device adverse event reports of problems that stem from absent and inadequate labeling, and misinterpretations of the information in the labeling. FDA continues to receive recall notifications from manufacturers that state labeling as the root cause of the problem being addressed in the recall.

To date, FDA has compiled information from two previously approved device studies regarding health care practitioners and device labeling. Phase 1: The first phase of the study was focus groups of approximately 100 practitioners to ask them what they thought of device labeling, what they used it for, when they used it, and how useful it was (under generic OMB control number 0910-0497). They responded that many times they couldn't find the labeling because it was separated from the device; when they used the labeling, it was to find something that they weren't aware of; and many times they couldn't find the information they wanted or found it difficult to use the labeling because the information was not in the same place for each device. The stated they would prefer to have labeling with a standard content and in a standard format. They also stated they wanted an abbreviated version of the full product labeling to be used as a reference for the critical operating and safety information for the device. Phase 2: The second phase of the study (OMB control number 0910-0715) was developed and implemented based on the information we received in Phase 1. We developed 3 prototypes of a generic infusion pump's abbreviated version of labeling and had 600 health care practitioners respond to survey questions regarding the content and the formatting of the labeling. Their responses were favorable to having a standard way of finding the information they wanted and a standard way of formatting the labeling.

We presented the results of the phased study at a public meeting in April 2013. One of the comments we received after presenting the information, was the need to take our research one more final step. The person stated that FDA needed to study if information is easier to find in a standard content and format versus what exists in labeling now. She further stated that, the information provided in the two research studies was compelling, but really needed the final step in order to validate our thinking. We agreed that this was needed.

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 human prescription drug and biological products became effective June 30, 2006. We are proposing to do the same type of study for medical device labeling.

Building upon the research methodology and success of the approach FDA used to evaluate drug labeling, we propose to measure the usability and usefulness of a draft standard content and format of device labeling against existing manufacturer labeling of the same device. This will support our research that has already been done to assess whether HCPs find the format and content of device labeling to be 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 compare existing device labeling from approximately six different types of medical devices with a standard content and format of the same

labeling that FDA researchers will develop using the existing labeling as their source of the information.

This final phase of the device labeling format and content is being conducted through funding from the CDRH Critical Path Initiative and the Entrepreneurs in Residence Program, using special government employees to develop the protocol, scenarios, and draft standardized labeling, pursuant to FDA's statutory authority to conduct and support research on the safety and efficacy of medical devices.

This information is not related to the American Recovery and Reinvestment Act of 2009.

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) 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 and recalls. 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.

Respondents are individuals.

3. Use of Improved Information Technology and Burden Reduction

Data will be collected at three different sites including two area hospitals using their devices, existing labeling, and HCPs. We will conduct the studies at the hospitals and ask the HCP to find information in the existing labeling and draft standardized labeling using various scenarios. The scenario will depend on the type of device labeling we are studying at that time. For example, if we are evaluating labeling for a ventilator used at that facility, we will develop scenarios centered around the ventilator labeling and ask the HCP to react to the scenario using the ventilator labeling. We are also receiving medical devices at FDA from medical device industry representatives through a material transfer agreement. We will have HCPs come to FDA and follow scenarios based on the devices, their existing labeling, and draft standardized labeling.

The data collection will be conducted in person. Therefore, FDA estimates that none of the respondents will use electronic means to fulfill the information collection.

4. Efforts to Identify Duplication and Use of Similar Information

We performed literature searches, queried participants at the public meeting, and talked with other Federal staff working on similar issues and found that there are no similar data available to test existing device labeling with a draft standard content and format of the same labeling. 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 the FDA have been engaged in data collection efforts for 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. The Unique Device Identifier (UDI) regulation has specific content and formatting for device labels, but not for the instructions for use which is the focus of this study. We are assuring that any information on the label that may be in the instructions for use will be identified and defined the same way. The Global Harmonization Task Force (GHTF) study group 1 developed a standard content of device labeling; we mapped the information contained in this document with our draft content, but the information we are requesting is more detailed than this document.

5. Impact on Small Businesses or Other Small Entities

   None of the respondents are small businesses.

   This is a one-time interaction that will be voluntary for those who choose to participate, and the volunteers may be part of an HCP's practice. However, they will be doing the testing during their own time. Given the nature of this testing, we don't believe 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 and second phases of this study finished in the spring of 2013. Without this data collection, FDA will not receive the needed feedback from the HCP community about the usability and usefulness of standardized labeling. Without this final data collection, FDA will not have a measurable assessment of the possible link between medical device content and the risk of improper use of a medical device. 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 09/12/2014 (79 FR 54727). FDA used comments from the medical device industry, healthcare professionals, caregivers, and patients to help formulate the objectives and define the scope of this study. The received comments are followed by FDA's responses as indicated below:

(Comment 1) One comment stated that FDA should coordinate with ASTM as they already have published a consensus standard (F2943) on this topic. This standard resulted from the work of a multi-stakeholder working group.

FDA reviewed the consensus standard (F2943) when we drafted the outline for this study. We consulted with a member of the ASTM committee. We also requested a member of the committee to be on our strategic planning committee for this study.

(Comment 2) A comment stated that FDA does not follow the guidance on formative human factors and usability studies. The guidance provides good direction on appropriately choosing representative end users, replicating the intended user environment and evaluating the user-product interface (see FDA draft guidance "Applying Human Factors and Usability Engineering to Optimize Medical Device Design" issued on June 22, 2011).

FDA had designed the protocol for this study with a human factors expert and a social scientist. In this particular study, we will be doing a cognitive test of the health care practitioners. They will be asked to find a piece of information in the draft outline of standard content of labeling, or in the manufacturer's existing labeling. They will not be interacting with the device and this will be a usability test; they will be responding to scenarios to search for information.

(Comment 3) One comment stated that FDA should ask the question, particularly to physicians, whether the standard of care requires them to read the user instructions and understand the product's warning.

This study is the third part of a three-part study. FDA performed focus groups of health care practitioners asking them what they want in labeling, where do they find labeling, what are the most important sections of labeling, and whether they even look at labeling. Their responses indicated that they do not look at labeling because it is complicated and they typically cannot find the information they want in one section. They stated they would like an abbreviated version of labeling in order to find use information more easily, they would like a standard content of labeling, and they also would like to find it electronically and in one place if possible.

FDA does not regulate the practice of medicine; we do, however, regulate labeling that accompanies a device. Based on the previous phases of the studies already done, we now want to test a standard content of labeling against an existing piece of the same labeling to see if health care practitioners can find what they need in a consistent and easy way. This is a cognitive testing of a standard content of labeling and does not include questions regarding whether or not someone is required to read the labeling before using the device.

We will be using outside experts to develop the protocol, develop the scenarios, develop the draft standardized labeling, perform the testing, and provide a summary of the study.

This is being done through the Entrepreneurs in Residence program that is funded by the White House to use outside experts and their special knowledge and skills to work on an innovative idea that helps the government when faced with a unique problem. Dr. Daryle Gardner-Bonneau is a renowned social scientist and human factors specialist who has worked with the device industry, standards organizations, and the National Research Council on issues with medical device labeling. Patricia Kingsley is a former FDA employee who worked on medical device labeling issues. Nancy Ostrove is a former FDA employee who worked on surveys and studies with drug community when CDER was developing standardized labeling for drugs. Dr. Ruth Day, a social scientist researcher at Duke University, has worked as a special government employee on the labeling for drugs. Ron Charnock is CEO of Kwikpoint, which is a visual language developer for instructions for use. His company worked on a Cooperative Research and Development Agreement with CDRH to determine if visual language could be used in lieu of words on certain portions of device labeling.

9. Explanation of Any Payment or Gift to Respondents

Participants in the testing will receive a token of appreciation for their participation in the study. We propose providing physicians a $200 incentive, nurses a $150 incentive, and technicians a $100 incentive. This amount is appropriate and necessary to gain cooperation from practitioners who have demanding work schedules and significant competing demands of their time. Practitioners are frequently approached to participate in research projects, making them more reluctant to participate. Incentives improve study cooperation among allied health workers (Delnevo, Abatemarco, and Steinberg, 2004). The incentive will be provided via a non-retailer specific electronic gift card.

10. Assurance of Confidentiality Provided to Respondents

The data from this study will be kept private to the fullest extent allowed by law. Individuals will be assured of the confidentiality of their replies under Section 934(c) of the Public Health Service Act, 42 USC 299c-3(c). They will be told the purposes for which the information is collected and that, in accordance with this statute, any identifiable information about them will not be used or disclosed for any other purpose.

For the in-hospital respondents, all materials including the cover letter and questionnaire will be reviewed and approved by the hospital's Institutional Review Boards (IRB). In instances where participant identity may be needed, the information collection will fully comply with all respects of the Privacy Act.

11. Justification for Sensitive Questions

The survey does not include questions that are 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

This study compares existing device labeling from approximately 6 different types of medical devices with a standard content and format of the same labeling that FDA researchers will develop using the existing labeling as their source of the information.

Building upon the research methodology and success of the approach FDA used to evaluate drug labeling, we propose to measure the usability and usefulness of a draft standard content and format of device labeling against existing manufacturer labeling of the same device. This will support our research that has already been done to assess whether HCPs find the format and content of device labeling to be clear, understandable, useful, and user friendly (OMB control number 0910-0715). Findings will provide evidence to inform FDA's planned regulatory approach to standardizing medical device labeling across the United States.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden

Type of Respondent	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours[1]	Capital Costs
Screener	60	1	60	0.08	5	
Health care professionals participating at a hospital	24	1	24	1.5	36	
Health care professionals participating at FDA	12	1	12	3.5	42	$240
Total					83	$240

[1] Numbers have been rounded.

We plan to screen approximately 60 potential respondents prior to being included in the study. The screener will be done using email. We estimate that the screener will only take approximately 5 minutes per person.

We will conduct the studies at three different sites including two area hospitals using their devices, existing labeling, and HCPs. We expect that the maximum time for testing will be 1.5 hours. Given a sample of 6 devices with 2 different labeling types, there will be 12 different labeling types to be tested. We plan to have 24 people test each type of the labeling.

We will also conduct the studies on FDA's campus using medical devices received from medical device industry representatives through a material transfer agreement. To account for travel time we have included 2 additional hours per response in the burden estimate for the 12 health care professionals participating at FDA.

12b. Annualized Cost Burden Estimate

We expect the largest number of participants will be registered nurses and estimate that 60% will be registered nurses, 30% will be technicians or therapists, and 10% will be

physicians. We calculated our estimate using the May 2013 wage estimates issued by the Bureau of Labor Statistics (http://www.bls.gov/oes/current/oes_nat.htm) for "Registered Nurses" (occupation code 29-1141), "Therapists, All Other" (occupation code 29-1129), and "Physicians and Surgeons, All Other" (occupation code 29-1069), respectively.

Type of Respondent	Total Burden Hours*	Hourly Wage Rate	Total Respondent Costs
Registered Nurses	50	$33.13	$1,656.50
Technicians or Therapists	25	$28.18	$704.50
Physicians	8	$90.00	$720.00
Total			$3,081.00

* Total burden hours for each occupation type are based on a percentage of the total estimated burden hours. Numbers have been rounded.

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

We have included $20 per respondent in the burden estimate to account for travel costs for health care professionals participating at FDA. This estimate assumes that the participants will be traveling from within 1 hour of FDA's campus via car, bus, or Metro.

14. Annualized Cost to the Federal Government

Costs to the government include the time required for monitoring and facilitating the study, providing regulatory expertise, and developing material transfer and confidentiality agreements. FDA estimates that five full time equivalent (FTE) positions consisting of a combination of professional and support staff are required for reviewing and processing the notifications and that this will take approximately 75 days. Based on an annual cost of $283,487 per position (which is the agency's projected average cost of an FTE including their benefits*), the rate is approximately $1,088 per day. Therefore, the estimated annual Federal cost is $408,000 ($1,088 x 5 FTEs x 75 days).

*Based on the Department of Health and Human Services, Fiscal Year 2015, Food and Drug Administration, Justification of Estimates for Appropriations Committees--ALL PURPOSE table (pp. 11-13).

15. Explanation for Program Changes or Adjustments

This is a new data collection. However, since publication of the 60-day notice, we have determined that it is necessary to screen respondents to determine eligibility for the study, i.e., respondents are health care practitioners who are users or potential users of at least one of the medical devices being tested. We plan to screen approximately 60 potential respondents. The screener will be done using email. We estimate that the screener will only take approximately 5 minutes per person, for a total of 5 additional burden hours.

Additionally, since publication of the 60-day notice, we have adjusted the number of respondents participating at hospitals versus those participating at FDA. Previously, we estimated a total of 38 respondents, 8 at a hospital and 30 at FDA. We now estimate that there will be 36 respondents, with 24 participating at a hospital and only 12 traveling to

FDA's campus. This adjustment reduces the hour burden as well as the cost of local travel.

16. Plans for Tabulation and Publication and Project Time Schedule

This is a cognitive human factors study to compare a proposed standardized content of medical device labeling to current manufacturer device labeling in terms of usability and location of key pieces of information. A methodology report that details information collection procedures will be prepared. There will also be a quantitative comparison between the standardized and current labeling for the time it takes an HCP to identify the appropriate location for a piece of information. The key findings of the comparison and the data acquired will be used to create a brief analytical report and a set of recommendations for any changes in device label formats.

Anticipated schedule of data collection tasks

Task	**Begin**	**End**
Submit to IRBs in hospitals	June 1, 2015	June 30, 2015
Prepare for data collection (MTAs, team meets, decide on device types, meet with hospitals, gather testers, develop draft labeling)	June 1, 2014	May 30, 2015
Main data collection	July 1, 2015	August 31, 2015
Edit and submit final data	September 1, 2015	September 30, 2015

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.