4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-1219]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Survey of Health Care Practitioners for Device Labeling Format and Content

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to oira_submission@omb.eop.gov. All comments should be identified with the title Survey of Health Care Practitioners for Device Labeling Format and Content. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Survey of Health Care Practitioners for Device Labeling Format and Content--21 CFR Part 801

(OMB Control Number 0910-NEW)

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.

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 health care practitioners (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.

In the Federal Register of September 12, 2014 (79 FR 54727), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA used comments from the medical device industry, health care 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 follows:

(Comment 1) One comment stated that FDA should coordinate with the American Society for Testing and Materials (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.

(Response) 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).

(Response) 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.

(Response) 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 the Center for Drug Evaluation and Research 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 the Center for Devices and Radiological Health to determine if visual language could be used in lieu of words on certain portions of device labeling.

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.

Dated: March 31, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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