4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0766]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Survey of "Health Care Providers' Responses to Medical Device Labeling"

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 OMB control number 0910-NEW and title "Survey of 'Health Care Providers' Responses to Medical Device Labeling'"). Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

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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 Providers' Responses to Medical Device Labeling"--21 CFR Part 801

(OMB Control Number 0910-NEW)

The purpose of this study is to determine the most effective device labeling format and inform an FDA's regulatory approach on standardized device labeling. Building upon the research methodology and success of the approach FDA used to evaluate drug labeling, we propose to ask health care providers (HCPs) to evaluate the quality of labeling (e.g. instructions for use, directions) 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 regulatory approach to standardizing medical device labeling across the United States.

In the Federal Register of November 1, 2011 (76 FR 67459), FDA published a 60-day notice requesting public comment on the proposed collection of information.

Two comments were received, however only one was related to the Paperwork Reduction Act of 1995. 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.

(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 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.

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

Table 1.--Estimated Annual Reporting Burden[1]

Respondents	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Interviews					
Physicians	6	1	6	1	6

Table 1.--Estimated Annual Reporting Burden[1]

Respondents	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Advanced practice nurses (NPs) and registered nurses	9	1	9	1	9
Medical technicians	9	1	9	1	9
Subtotal	24	1	24	1	24
Survey					
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	624	1	624	0.5	324

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

Dated: February 27, 2012.

David Dorsey,

Acting Associate Commissioner for Policy and Planning.

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