4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

Agency Information Collection Activities; Proposed Collection; 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 an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the Federal Register concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on the proposed information collection "Survey of Health Care Practitioners for Device Labeling Format and Content."

DATES: Submit either electronic or written comments on the collection of information by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit electronic comments on the collection of information to http://www.regulations.gov. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the 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: Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

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.

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

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

Type of Respondent	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours	Capital Costs
HCPs participating at a hospital	8	1	8	2	16	
HCPs participating at FDA	30	1	30	4	120	$600
Total					136	$600

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

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 2 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 eight 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 and cost, we have included 2 additional hours and $20 per respondent in the burden estimate for HCPs participating at FDA.

Dated: September 5, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014-21725 Filed 09/11/2014 at 8:45 am; Publication Date: 09/12/2014]