

Estimated Total Annual Burden Hours: 2,850.

Additional Information

Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: infocollection@acf.hhs.gov.

OMB Comment

OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project. Fax: 202-395-7285. Email: OIRA_SUBMISSION@OMB.EOP.GOV. Attn: Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2012-4973 Filed 2-29-12; 8:45 am]

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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 April 2, 2012.

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 oir_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: Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-5156, Daniel.Gittleson@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 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 BURDEN¹

Respondents	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Interviews					
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
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.

[FR Doc. 2012-4969 Filed 2-29-12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Notice Correction; A Multi-Center International Hospital-Based Case-Control Study of Lymphoma in Asia (AsiaLymph) (NCI)

The **Federal Register** notice published on February 24, 2012 (77 FR 11136) announcing the submission to OMB of the project titled, “A multi-center international hospital-based case-control study of lymphoma in Asia (AsiaLymph) (NCI)” was submitted with an error. The “*Type of Information Collection Request*” was incorrectly listed as an Emergency. This submission should be considered a new submission.

Dated: February 24, 2012.

Vivian Horovitch-Kelley,

NCI Project Clearance Liaison, National Institutes of Health.

[FR Doc. 2012-4884 Filed 2-29-12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: AIDS and Related Research Integrated Review Group, NeuroAIDS and other End-Organ Diseases Study Section.

Date: March 20, 2012.

Time: 8 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: Sheraton Delfina Santa Monica Hotel, 530 West Pico Boulevard, Santa Monica, CA 90405.

Contact Person: Eduardo A. Montalvo, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5108, MSC 7852, Bethesda, MD 20892, (301) 435-1168, *montalve@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Member Conflict: Cognition, Perception and Speech.

Date: March 20, 2012.

Time: 3 p.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Weijia Ni, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3184, MSC 7848, Bethesda, MD 20892, (301) 237-9918, *niw@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Review of Behavioral and Social HIV/AIDS RFA Applications.

Date: March 21, 2012.

Time: 1 p.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: Sheraton Delfina Santa Monica Hotel, 530 West Pico Boulevard, Santa Monica, CA 90405.

Contact Person: Mark P. Rubert, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5218, MSC 7852, Bethesda, MD 20892, 301-435-1775, *rubertm@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Member Conflict: Learning and Memory.

Date: March 21, 2012.

Time: 1 p.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: M. Catherine Bennett, Ph.D., Scientific Review Officer, Center for