DEPARTMENT OF HEALTH & HUMAN SERVICES Food and Drug Administration

Memorandum

Date October 25, 2010

From PRA Specialist, Paperwork Reduction and Records Management Staff
Office of Information Management

Subject Request for OMB Approval of FDA Focus Group Sessions on "Health Care Practitioners' Responses to Medical Device Labeling"
OMB Control No.0910-0497

To Human Resources and Housing Branch
Office of Information and Regulatory Affairs, OMB

Through HHS Reports Clearance Officer _____

Need for survey: The Center for Devices and Radiological Health (CDRH) is currently working on an initiative to establish uniform content and format requirements for the labeling (instructions for use) of medical devices. As part of this initiative, CDRH is seeking OMB approval under the generic clearance 0910-0497 to conduct focus groups on "Health Care Practitioners' Responses to Medical Device Labeling". The responses obtained from the focus groups will help us identify which sections of the labeling/instructions are most important to HCPs for the safe use of medical devices, which parts or sections, if any, could be omitted, and what might be missing from current labeling. The resulting opinions from the focus groups will be used to inform CDRH about the utility of current labeling/instructions for use for select medical devices, provide insight for approaches to take in the development of standardized and user-friendly labeling/instructions and facilitate additional research in moving towards the goal of providing labeling/instructions for the safe use of medical devices.

How, by Whom, and for What Purposes the Data Will be Used:

There will be a total of nine focus groups with approximately eight to ten participants in each focus group. The focus group participants will represent one of three medical specialty areas: respiratory care, wound care, and infusion therapy. Three focus groups will be conducted in three different geographic areas in the eastern portion of the United States. For each location, there will be one group of prescribing health care practitioners such as physicians and nurse practitioners; there will be a second group of registered

nurses; and, there will be a third group of specialists who represent one of the three aforementioned medical specialties. They will be selected through a screening process developed by the contractor, RTI International (See Appendix A). They will be selected using the following selection criteria: from a wide variety of clinical practices, years of experience, and whether or not they have recently participated in a government-sponsored focus group session.
These focus group sessions, if started at the beginning of the calendar year 2011, should be finished within 16 weeks. Responses will be collated and de-identified upon submission to the FDA within 6 weeks from the end of these sessions. These responses will be an important contribution in the development of a standard content and format for device labeling. The second phase of this project is to develop 3 templates for practitioners to review and determine if they are sufficient for device labeling; responses in Phase I (focus group sessions) are crucial to the success of Phase II.

Burden:

The focus group moderated sessions will last 90 minutes. At an average of nine respondents in each of nine focus groups, we estimate the total burden to be 122 hours. Please see Appendix B for the moderator's guide and Appendix C for the 13 leading labeling terms we are supplying for the moderator.

Table 1. Estimated Burden for Selected Respondents

No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
81	1	81	1.5	122

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

Efforts to Identify Duplication:

When writing the task order for this contract, CDRH reviewed any other ongoing projects related to medical device labeling for the health care practitioner. There is nothing that exists and the only other study done on medical device labeling was a focus group done on a limited scale in 1995. At this time, no other part of the agency is collecting this type of data related to medical device content of labeling.

Consequences to FDA if the Collection is not Conducted

Without this data collection, FDA will not receive feedback from the professional user community about how they use device labeling and how they want to see device labeling developed for the future. FDA is developing a standard content and format for device labeling and must know what the user community is thinking in this area before developing a standard device labeling template. This contract is a two-phased two-year contract of which the focus group is the first phase. The second phase depends on the results of the first phase.

Explain any decision to provide any payment or gift to respondents:

The contractor who is conducting these focus group sessions will give an incentive to the participants within the going rate for focus group participants. The incentive structure is: $250.00 for prescribing health care professionals, $150.00 for registered nurses, and $100 for medical technical specialists. Three focus groups will be prescribing health care professionals and they typically receive more payment as an incentive than other focus group participants because it is difficult to convince them to participate especially during their off-hours. The three focus groups for registered nurses and the three focus groups for specialists will receive a lower amount given that they are easier to recruit and their salaries are typically lower than prescribing health care professionals. These incentives reflect the value that a focus group participant places on their free time.

The consequences of an insufficient incentive include: more time and cost to recruit; a better chance of "no-shows" after they consent to participate; and the increased probability that a focus group may need to be cancelled or postponed due to insufficient numbers of people recruited for that group. This incurs more cost because of rescheduling and new recruitments.

Confidentiality of Respondents:

There are no questions of a sensitive nature. The participants are assured their responses will be kept confidential when they agree to participate in a session (See Appendix D for the consent form). Participation is voluntary. Respondents will also be asked to fill out a brief questionnaire to help FDA gather more information about their backgrounds. This is voluntary and will be handed out toward the end of the focus group session (See Appendix E).