FDA DOCUMENTATION FOR THE GENERIC CLEARANCE OF TESTING COMMUNICATIONS ON MEDICAL DEVICES AND RADIATION-EMITTING PRODUCTS (0910-0678)

TITLE OF INFORMATION COLLECTION: Consumer Responses to Medical Device Labeling

DESCRIPTION OF THIS SPECIFIC COLLECTION

1. **Statement of need:**

The Center for Devices and Radiological Health is seeking OMB approval under the generic clearance 0910-0678 to conduct a survey to learn of consumers' feedback on medical device labeling. CDRH is currently involved in an initiative to establish uniform content and format requirements for medical device labeling. A survey like this one is an important method to identify which sections of the labeling are most important for consumers for the safe use of medical devices, and which parts, if any, could be omitted, or to identify what might be missing from current labeling. Through the results from survey, CDRH will be able to inform decisions on approaches to modify existing labeling instructions to make them standardized and user-friendly for consumers.

The FDA seeks to understand consumers' labeling needs by gathering information to gauge which medical device labeling elements are most relevant and most important to consumers to help them operate and use a medical device safely and effectively. Additionally, the FDA continues to receive medical device adverse event reports of problems that stem from absent labeling, or misinterpretations of the information in labeling from its Medical Device Reporting program. Due to the level of concern at the FDA about medical device labeling, a Center-wide Team has been established to examine this issue. The results of this data collection, in addition to other data sources, will assist the team as it formulates next steps.

2. **Intended use of information:**

FDA scientific analysts will review the results from the survey. If the FDA believes there is a significant risk, as noted from the survey, it will combine those results with data gained from the other sources cited above. The FDA will work with the necessary stakeholders to make important information known.

3. **Description of respondents:**

NFCA represents approximately 17000 family caregivers.

4. **Date(s) to be Conducted:**

September 20th 2011-December 13th 2011

5. **How the Information is being collected:**

Participation in this survey is voluntary and the respondents will remain anonymous. Responses to the survey cannot be linked to the respondent list. The National Family Caregivers Association (NFCA) respondents will be asked to complete the survey online. As previously discussed, SSS will develop an online questionnaire to be linked to NFCA's listserv communication. Interested respondents can click on the URL provided. They will be directed to the survey questions and can provide answers to the survey questions online. All survey results will be collated and analyzed by MedSun Contractor, SSS. The respondents will be de-identified by SSS. This survey will provide vital information to the FDA experts who convened to determine medical device labeling needs. The survey will be provided for 12 weeks.

6. **Confidentiality of Respondents:**
The survey will be distributed to NFCA members. Please see Attachment B, which identifies and provides additional information about the organization that is willing to collaborate with the FDA. The NFCA is willing to work with their respective membership.

The respondents will be de-identified by MedSun Contractor, Social & Scientific Systems (SSS), who will be administering the survey questions. If the FDA requires any follow-up on the response, we can go back to the respondent through SSS – but FDA will still be unaware of the identity of the responder. Once the project ends, the contractor will destroy all documents that contain the respondents' identities.

7. **Amount and justification for any proposed incentive**
FDA will not be providing any incentives.

8. **Questions of a Sensitive Nature**
There are no questions of a sensitive nature. The participants are assured their responses will be kept confidential if they decide to participate in the survey. Participation is voluntary.

9. **Description of Statistical Methods**
FDA is proposing to use an electronic on-line survey and telephone surveys. The FDA proposes to administer this survey to the NFCA.

Survey method: Online survey accessible from NFCA listserv, which is distributed to 500 members. The MedSun Contractor, SSS will develop an online questionnaire to be linked to this organization's listserv communication vehicle. Interested respondents can click on the URL provided. They will be directed to the survey questions and can provide answers to the survey questions online. All survey results will be collated and analyzed by SSS. As mentioned, the respondents will be de-identified by SSS.

The survey data is not intended to provide an estimate of incidence. Because this proposed data collection is qualitative, and because the FDA resources for processing incoming data are limited, the FDA will administer this survey with the prior understanding that the questions may not be pertinent to all the respondents, and that not all of the respondents to whom they are pertinent will reply. For example, not all 500 listserv members care for patients who require medical devices and of the group who do, only a portion will respond. However, for burden estimates, we will use the total number of listserv members.

BURDEN HOUR COMPUTATION *(Number of responses (X) estimated response or participation time in minutes (/60) = annual burden hours):*

Method	Number of Respondents	Number of Minutes	Total Burden Hours
Online survey	500	30 minutes (.50)	250
Total	500		250

REQUESTED APPROVAL DATE: September 15th 2011

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