Reference OMB NO: 0910-0500

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service
Food and Drug Administration

Memorandum

Date November 12, 2009

From Chief, PRA and Records Management Branch

Subject Request for OMB Approval of Rapid Response Survey for "Negative Pressure Wound Therapy Device Used in the Home Environment"
Reference OMB NO: 0910-0500

To Chief, Human Resources and Housing Branch
Office of Information and Regulatory Affairs, OMB
Through: Reports Clearance Officer, HHS _____

Pursuant to the Terms of Clearance for information to be collected in the Rapid Response Survey, FDA is sending a copy of the complete survey and justification information for OMB 10-day review prior to data collection.

Justification:

1. Need for survey: The FDA has received reports of deaths and serious injuries with products that migrate into the home and other extended care facilities, specifically with negative wound therapy systems.

   The following bullets summarize reported device and patient problems with negative wound therapy systems:

   - Bleeding is the most serious adverse event which indicates 7 reported deaths and 17 injuries.
   - Treatment of these patients included a visit to the Emergency Room, hospitalization, additional surgical procedures and blood transfusions.
   - Extensive bleeding occurred at lower extremity vascular graft sites. Other events occurred during dressing change due to foam adhesion to the wound.
   - Majority of events occurred either at home or in long term care facilities.

The FDA currently has insufficient information to gauge whether or not these types of issues are rare events or occur more frequently. With this data collection, the FDA seeks to understand the nature of the problem and attempt to determine if the problem is a widespread public health issue. Due to the level of concern at the FDA about these devices, a Center-wide Network Team has been established to examine this issue. The results of this data collection, in addition to other data sources, will assist the Network Team as it formulates next steps. A copy of the Rapid Response Survey is submitted as Attachment A.

2. How, by Whom, and for What Purposes the Data Will be Used:
The FDA requires more information to understand whether these medical devices pose a public health issue. We would like to survey members belonging to a home care professional organization to learn of provider experiences with these devices, specifically about the nature and frequency of these types of adverse events. We would also like to survey professional organizations specific to wound care about the nature and frequency of complications with the use of these negative wound therapy systems in the home environment. This survey would permit us to collect data from a purposeful sample.

   This Rapid Response Survey is one of many tools the Agency is using to evaluate the public health impact of the potential problems associated with the use of these devices. Additionally, the FDA continues to receive medical device adverse event reports of problems from its Medical Device Reporting program. The FDA will also continue to make use of the literature and other published information.

   FDA scientific, medical and engineering analysts will review the results from the Rapid Response Survey. If the FDA believes there is a significant risk of adverse events occurring, as noted from the Rapid Response Survey, it will combine those results with data gained from the other sources cited above. The FDA will work with the manufacturers and health care professional organizations to make important information known to the clinical community. Additionally, the FDA will work with manufacturers to ensure the development, testing and promulgation of methods for reducing the risk associated with these devices and to minimize the complications from adverse events that may occur in the course of usage, specifically from usage in the home setting.

3. Describe Efforts to Identify Duplication:
No other part of the agency is collecting this type of data related to safe and effective use of negative pressure wound therapy systems in the home environment.

4. Consequences to FDA if the Collection is not Conducted:
Without this timely data collection, it could take many months, or even longer, for the FDA to obtain enough spontaneous adverse event reports to know the extent of the patient harm from this situation. It is important to the public health to discern these issues rapidly so the FDA may work with the manufacturers and health care professional organizations to determine the most appropriate means to communicate

the information to the clinical community so serious injuries due to this problem may be avoided, especially because of the uniqueness belonging to this specific patient population, who reside in the home.

5. Efforts to Consult with Persons Outside the Agency:
   FDA consulted with 1 person at 7 different professional organizations whose memberships work with these products. Three of these organizations volunteered to help the FDA further understand the risk associated with these systems. See 9a for more details.

6. Explain any decision to provide any payment or gift to respondents:
   It is not FDA policy to pay or provide gifts to Rapid Response Survey respondents.

7. Confidentiality of Respondents:
   The survey will be distributed to healthcare professional organizations, specifically those with members who specialize in home care and wound care. Please see Attachment B, which identifies and provides additional information about the organizations we have contacted as well as those who are willing to collaborate with the FDA. The National Association for Home Care and Hospice (NAHC), the Association for the Advancement of Wound Care (AAWC), and the Alliance for Wound Care Stakeholders (AWCS) are the three organizations from this listing, who are willing to work with their respective memberships. 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.

8. There are no questions of a sensitive nature.

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 National Association for Home Care and Hospice (NAHC).

   Survey method: Online survey accessible from NAHC listserv and daily electronic newsletter, which is distributed to 5000 members. The MedSun Contractor, SSS will develop an online questionnaire to be linked to this organization's listserv and electronic newsletter communication vehicles. 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.
   - Association for the Advancement of Wound Care (AAWC)

   Survey method: Moderated telephone survey (10 surveys)
   - Alliance of Wound Care Stakeholders (AWCS)

   Survey method: Moderated telephone survey (10 surveys)

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 5000 listserv members use the NPWT system and of the group which has used it, only a portion will respond. However, for burden estimates, we will use the total number of listserv members.

a. Respondent Universe

- NAHC represents approximately 5,000 home health and hospice providers. The providers range from small 'mom and pop-like' operations to large publically traded corporations, with multiple agencies.

- The Association for the Advancement of Wound Care (AAWC) is the preeminent multidisciplinary organization for wound care. We will contact 10 of its members to respond to the telephone survey. These respondents will be selected based on referrals made by the president of AAWC, with whom we have been communicating.

- The Alliance of Wound Care Stakeholders (AWCS) is a multidisciplinary consortium of 17 physician, clinical, provider, patient and manufacturer organizations that addresses regulatory and legislative issues impacting wound care. Its mission is to promote quality care and patient access to wound care products and services. We will contact 10 of its members to respond to the telephone survey. These respondents will be selected based on referrals made by the Executive Director of AWCS, with whom we have been communicating.

b. Information Collection Procedures

Participation in this survey is voluntary and the respondents will remain anonymous. Responses to the survey cannot be linked to the respondent list. NAHC respondents will be asked to complete the survey online. As previously discussed, SSS will develop an online questionnaire to be linked to NAHC's listserv communication and daily electronic newsletter. 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 if this is a public health issue. The survey will be provided for 4 weeks. AAWC and AWCS members (10 from each group) will take the telephone survey.

c. Expected response rate

A 70% response rate is expected. The impact of a lower response rate to this questionnaire will be considered before FDA takes action to improve the response

rate. The FDA may determine that a public health problem may exist based solely on information provided by these professional organizations. The individuals analyzing the responses are clinical experts in the devices surveyed. Therefore, if the response-rate to this survey is lower than 70%, but a problem-pattern is noted in the obtained responses, the FDA may not require non-response follow-up to determine that this particular problem must be further investigated to determine how the issue should be addressed. The goals of this information collection may be met without additional follow-up. The Rapid Response Survey is only one tool the Agency is using to evaluate the public health impact of this potential problem.

d. Estimate of burden:

When the original supporting statement was sent to OMB, it was estimated that the maximum time for reporting burden for any given Rapid Response Survey would not exceed 2 hours. Of course, some surveys will take longer than others to complete, depending on the complexity of the public health issue under evaluation.

It is estimated that this particular survey will take no longer than 30 minutes to complete. Given a sample of a possible 5020 respondents to be surveyed, this gives a burden of 2510 hours. It is unknown how many of these providers will respond to the on-line rationale questionnaire from FDA, but to provide a conservative estimate of burden, the burden numbers are based on the full complement responding.

Method	Number of Respondents	Number of Minutes	Total Burden Hours
Online survey	5000	30/60 minutes	2500
Phone	20	30/60 minutes	10
Total	5020	30/60 minutes	2510