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

Memorandum

Date June 24, 2009

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

Subject Request for Approval of FDA Focus Group, "Risk Managers' Focus Group: Adverse Event Reporting Practices for Tissue and Cell Products"; OMB Control No. 0910-0497

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

The Food and Drug Administration (FDA), Center for Biologics Evaluation and Research, Office of Biostatistics and Epidemiology is seeking OMB approval under the generic clearance 0910-0497 to conduct a focus group entitled, "Risk Managers' Focus Group: Adverse Event Reporting Practices for Tissue and Cell Products." The purpose of the focus group is to understand how hospitals identify adverse events following the use of human cells, tissues, and cellular and tissue based products (HCT/Ps) and what factors influence hospital personnel to report or not report such events. Because a risk manager's primary aim is to detect, evaluate and prevent risks, we are interested in learning about the practices of risk managers and other multidisciplinary health care professionals in their facilities.

In the past year, we have conducted two other focus groups on adverse event reporting for HCT/Ps, one with orthopedic surgeons and one with infection control managers. The objective was to understand how hospitals identify adverse events following the use of HCT/Ps and the factors that influence reporting. A total of less than 10 individuals participated in these two groups. In this third focus group, the participants will be risk managers and other healthcare professionals, including infection control practitioners, healthcare providers, operating room managers, or other hospital personnel without any restriction to sex or age.

The focus group will explore hospital practices for detecting, evaluating, and preventing tissue and cell product adverse events in their facilities. The focus group will assess how risk managers learn of adverse events after tissue allograft transplantation at their facility and how the facility investigates these events. Participants will also be asked about possible barriers to reporting adverse events to FDA and their awareness of Joint Commission and FDA regulations regarding adverse event reporting.

An agenda and fictitious clinical vignettes (attached) to be presented to the group prepared by CBER will be used by the contractor (Social and Scientific Systems) to facilitate the guided discussion. The participants of the focus group will be adults, at least 18 years of age, recruited from hospitals registered in the Medical Product Surveillance Network (MedSun), a surveillance program sponsored by CDRH that includes 350 healthcare facilities nationwide. The contractor will recruit participants by contacting MedSun representatives at hospitals

participating in the MedSun surveillance program and asking for volunteers. Other than FDA and contractor staff, no more than 10 individuals will participate in this focus group. Participants will receive a gift with a dollar amount not to exceed $75.00 as an incentive for participating in the focus group.

The focus group will be conducted via telephone conference for 90 minutes. The contractor performing the focus group will ensure that participants' identities and the identities of their institution are not revealed to any FDA personnel. There are no plans for future surveys after the completion of the focus group.

Other than FDA and contractor staff, no more than 10 individuals will participate in the focus group. Focus group participants must be risk managers or other healthcare professionals, including infection control practitioners, healthcare providers, operating room managers, infection control practitioners or other hospital personnel without any restriction on sex or age. The potential pool will be recruited from hospitals registered in the MedSun surveillance program sponsored by CDRH. Each participant will participate in one session lasting approximately 90 minutes.

The time required for recruiting and participation will be 2.0 hours per participant. There will be a total of no more than 10 participants in the focus group, producing a total estimated respondent burden of 20.0 hours.

Table 1. Estimated Annual Reporting Burden for Selected Respondents[a]

Number of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
10	1	10	2.0	20.0

The Office of Biostatistics and Epidemiology would like to begin the focus group early in September 2009.

The information gained from the focus group will help FDA to better understand how hospitals identify adverse events following HCT/Ps and the factors that influence hospital personnel to report or not report such events.

If you have any questions, please contact Jonna Capezzuto on 301.796.3794.

Attachments