DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

Date July XX, 2010

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

Subject Request for Approval of FDA Customer Satisfaction Survey, "OCTGT Regulatory Overview Web Seminar User Feedback Survey"; OMB Control No. 0910-0360

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

The Food and Drug Administration (FDA), Office of Cellular, Tissue, and Gene Therapies (OCTGT) within the Center for Biologics Evaluation and Research (CBER) is seeking OMB approval under the generic clearance 0910-0360 to conduct a customer satisfaction survey, "OCTGT Regulatory Overview Web Seminar User Feedback Survey." The survey will assess the effectiveness of a pilot web-based seminar as an educational outreach tool to provide clear information addressing frequently asked questions pertaining to the OCTGT regulatory process.

The purpose of the survey is to fulfill phase one of Executive Order 12862 that requires Federal Agencies to "survey customers to determine the kind and quality of services that they want and their level of satisfaction with existing services."

The survey proposed here will gather feedback on user satisfaction of a web-based educational video that OCTGT is developing. The proposed video seminar would be freely available on-demand through the FDA website, as a means of providing basic regulatory information to OCTGT stakeholders. The educational video is targeted to current and future sponsors of submissions to OCTGT, who are typically academic researchers or small companies with limited regulatory experience. The video would provide clear answers to frequently asked regulatory questions, such as describing the key components of a regulatory submission. The program will be modeled after an existing FDA outreach tool, called CDRH Learn (http://www.fda.gov/Training/CDRHLearn/ucm162015.htm), which has video, audio, text captioning, and companion slides. The content of the OCTGT web seminar will be drawn exclusively from and refer users to established regulations and guidance documents, all of which are already cleared and publicly available. The web-based video program will bring together information from those resources such that it is easily and efficiently accessed. Providing this content will ensure that OCTGT's outreach and communication efforts continue to reach a broad audience and, by referring sponsors to this resource, provide consistent information and reduce the human resource burden of responding to questions that will be addressed in this web seminar.

After viewing the pilot video, users would have the option of voluntarily participating in a brief customer satisfaction survey to provide input regarding the utility of this educational resource. The survey would be administered as a series of questions through the OCTGT website. The data from the responses to the survey would then be used to assess the value of this outreach tool and how to improve it. The voluntary survey will not ask for names or any personal information from the users. There will be a few general questions asked which will be valuable to the data analysis (e.g. what is the user's employment sector). Users will have the option of responding to questions that will assess satisfaction with the presentation format, content, level of detail, and if there are other regulatory topics of interest that were not covered. A draft of the survey questions is attached.

Since this is a new program for OCTGT, the number of users who will participate in the web seminar and, therefore, the survey is unknown. OCTGT has received an average of 145 new submissions per year over the past five years. A number of those sponsors request pre-submission meetings, in addition to informal calls and inquiries to OCTGT staff. The web seminar and associated user survey would be targeting those users, as well as those researchers who are just beginning to think about engaging in dialogue with the FDA and seek information in preparation. There is a significant perceived need, since roughly two-thirds of OCTGT sponsors are academic investigators, who typically have limited or no regulatory experience. By the end of the first year, OCTGT hopes to achieve 500 users of the web seminar, with a target of 325 respondents (65% response rate) to the survey. It is expected that completing the survey will take 8 minutes, for a total burden estimate of 43.3 hours.

OCTGT will take a number of steps to achieve the targeted response rate of 65%. OCTGT will include the link for the web-based seminar and the associated survey with all of its outreach efforts, including conference presentations, correspondence with sponsors, and through other appropriate mechanisms. OCTGT will include a request at the beginning of the web-based seminar asking users to participate in the voluntary follow-up survey. Through these efforts, OCTGT hopes to obtain 500 users by the end of the pilot year. In the event that the number of users and/or survey respondents is low at the end of the first year, these data may be factored into whether or not to continue the pilot program for a second year.

The survey will be conducted on an ongoing basis through the duration of the one year pilot of the web-based seminar project. There may be a future survey, depending upon the responses to this pilot project. The survey responses will be used to assess the value of the program to users to determine whether the program should be continued in its pilot form, modified, or expanded. If the program is continued beyond the first year, it is expected that the current survey will be continued. In the event that changes to the program are implemented in year two, it is possible that a replacement survey may be developed to collect user input on the updated content.

If you have any questions, please contact Elizabeth Berbakos at (301) 796-3792.

Attachments