0910-0497	02/28/2011	200803-0910-002	HHS/FDA	Risk Communication Strategies for Medical Countermeasure Distribution	Gen IC

Terms of clearance

This generic IC is approved under the umbrella generic ICR 0910-0497 on the understanding that this focus group will be assessing the FORMAT of the communication materials, rather than the CONTENT of the materials.

We further understand, pursuant to FDA memo of 1/20/2010 (excerpted below), that the qualitative data collected in this focus group will be the first step in preparing to modify fact sheets, and that further research will be conducted.

Finally, FDA is reminded to include all materials that will be used as part of the focus group in the ICR submission, including the fact sheets that will be shown to the study participants as part of this focus group.

FDA Memo of 1/20/2010

Qualitative date revealed in this focus group will be the first step in preparing to modify the fact sheets. Modifying the fact sheets will help to improve patient or family member comprehension of the content thus enabling patients to make improved decisions about health in the face of a public emergency.

Yes the format and content are separate issues in the fact sheets. Content of the fact sheets will be countermeasure dependent yet the format of the fact sheets will remain constant based on the results of this research. Programmatic requirements at the point of distribution limit the amount of content for logistical reasons, thus making the delivery of the limited information vitally important to the patient or family member. The purpose of the fact sheets is to help the patient or family member understand and weigh the risks versus the benefits of using the countermeasure regardless if the countermeasure is approved for use. For purposes of this research we will standardize the content enabling the participants to focus on the formatting.