CBER's Regulation of Biologics

Midthun

Welcome. I am Dr. Karen Midthun, the Director of the U.S. Food and Drug Administration's Center for Biologics Evaluation and Research or "CBER". I would like to introduce to you a web-based program that is intended to provide information on the work we do at CBER in our oversight of biological products in the United States. The program that follows was generated from a live program held with a group of foreign regulatory counterparts in October 2009. Some modest editing has been done to the 2009 talks in order to enhance the overall presentation of the program in the web format. I asked my staff to develop this web-based production in order to broaden its reach to those who have not been able to participate in the past or will not be able to participate in future live events.

I need to point out to viewers of the program that this is but a snapshot in time of our program that, over time, will become dated. We hope to refresh the program to keep pace with any changes to policy, regulations or legislation that will undoubtedly occur in the future. I hope you, our audience, find this program helpful. Thank you.