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## **The US FDA to Present at IBC's Global Follow-On Biologics Conference**

**WESTBOROUGH, MASS. — August 21, 2008---** IBC announced the dates for its upcoming **Global Follow-On Biologics Conference**. **The conference will be held** on November 17-18, 2008 at the Hyatt Regency in Bethesda, MD. The agenda includes presenters from organizations including **United States Food and Drug Administration, Genentech, Inc.** and **Sandoz International**.

**Barry Cherney, Ph.D.**, *Deputy Director, Division of Therapeutic Proteins, Office of Biotechnology Products, CDER, FDA* will discuss factors that need to be considered when evaluating the similarity of follow-on protein products his presentation "Product Quality Issues Surrounding Follow-On Biologics."

**Susan Kirshner, Ph.D.**, *Acting Associate Chief, Laboratory of Immunology, Division of Therapeutic Proteins, CDER, FDA* will provide a regulatory perspective on immunogenicity assessment as part of a protocol for establishing comparability following major manufacturing changes in her presentation "Immunogenicity of Biological Therapeutics Following major Manufacturing Changes."

### **Keynote Presentations:**

"The Follow-on Biologics Landscape: A Pioneer's Perspective on the Future"

**Joerg Windisch, Ph.D.**, *Head of Global Development Biopharmaceuticals, Sandoz International*

"The Follow-On Dilemma – A Global Perspective"

**Robert Garnick, Ph.D.**, *Senior Vice President, Regulatory, Quality and Compliance, Genentech, Inc.*

The mission of the **Global Follow-On Biologics conference is to** educate employees from both innovator and follow-on biologics companies on how to prepare for the follow-on biologics marketplace that will emerge once approvals are made by the US Government. Scientific experts, legal and financial professionals, and government officials will provide insight into regulatory guidelines and I.P. protection. In addition, representatives from **Health Canada** and **Probiomed, Mexico** will share their experiences.

For further information and to register for this event, please visit [www.IBCLifeSciences.com/FOB](http://www.IBCLifeSciences.com/FOB)

To apply for a press pass, please contact [gbroughton@ibcusa.com](mailto:gbroughton@ibcusa.com).

### **About IBC Life Sciences**

IBC Life Sciences is the worldwide leader in scientific, technological and business conferences and courses for the life science industry. To develop its programs, IBC actively researches the advancements, technologies and trends impacting and driving the race for new drugs and therapies. No other organization can make claim to the breadth and quality that IBC Life Sciences delivers in each event giving the company recognition around the globe for quality, service and value. For more information, visit: <http://www.IBCLifeSciences.com>.