

**FDA Workshop: Developing Rabies Monoclonal Antibody Products as a Component of Rabies Post-Exposure Prophylaxis**

**FDA White Oak Campus, July 17, 2017**

<b>Time</b>	<b>Topic</b>	<b>Speaker(s) and Affiliation</b>
7:30-8:30 am	<b>Registration</b>	
8:30-8:40 am	<b>Welcome and Panel Introductions</b>	Ed Cox, FDA
8:40-9:00 am	<b>Opening Remarks</b>	Sarah Connelly, FDA
9:00-9:15 am	<b>Background on Rabies Epidemiology and Vectors</b>	Louise Taylor, Global Alliance for Rabies Control
9:15-9:30 am	<b>Scientific Basis for Approval of Human Rabies Immunoglobulin in Combination with Rabies Vaccine</b>	Dorothy Scott, FDA
9:30-9:45 am	<b>Rabies Postexposure Prophylaxis: Global Perspective on the Current Standard of Care</b>	Henry Wilde, Chulalongkorn University, Bangkok
9:45-10:35 am	<b>Perspectives on Rabies mAb Development</b> <ul style="list-style-type: none"> <li>• <b>WHO</b> experience</li> <li>• <b>Example from Industry</b> experience</li> <li>• <b>Example from Academic</b> experience</li> </ul>	<b>WHO:</b> Erin Grace Sparrow <b>Industry:</b> Samir Desai (Zydus Cadila) and Bhagwat Gunale (Serum Institute of India) <b>Academic:</b> Beatriz Quiambao (Research Institute for Tropical Medicine, Philippines)
10:35-10:50 am	<b>Morning Break</b>	
10:50-11:20 am	<b>Use of Animal Models and Serologic Assays in Rabies Product Development</b>	<b>Animal Models:</b> James A. Ellison, CDC <b>Assays:</b> Susan Moore, KSU
11:20-12:35 pm	<b>Moderated Panel Discussion 1</b>	<b>Moderators:</b> Damon Deming, FDA Christine Fehlner-Gardiner, Canadian Food Inspection Agency
12:35-1:35 pm	<b>Lunch</b>	
1:35-2:00 pm	<b>Formal Public Comments</b>	
2:00-2:30 pm	<b>FDA Perspective on Rabies mAb Clinical Trial Challenges</b>	Tanvir Bell, FDA
2:30-2:45 pm	<b>Ethical Considerations in Rabies mAb Development</b>	Holly Taylor, Johns Hopkins University
2:45-3:00 pm	<b>Afternoon Break</b>	
3:00-4:30 pm	<b>Moderated Panel Discussion 2</b>	<b>Moderators:</b> Sarah Connelly, FDA George Siberry, U.S. Department of State
4:30-4:45 pm	<b>Closing Remarks</b>	Debra Birnkrant, FDA
4:45 pm	<b>Adjourn</b>	

All Panelists (including Speakers)

<b>WHO</b>	Erin Grace Sparrow
<b>CDC</b>	Jesse Blanton, Richard Franka, James Ellison
<b>Industry</b>	Deborah Molrine (MassBiologics); Samir Desai (Zydus Cadila), Bhagwat Gunale (Serum Institute of India)
<b>Health Departments</b>	Sally Slavinski (NY), Catherine Brown (MA)
<b>Individual Speakers/ Panelists</b>	Louise Taylor
	Beatriz Quiambao
	Susan Moore
	Christine Fehlner-Gardiner
	Holly Taylor
	Thomas Fleming
	Henry Wilde
	Geetha Srinivas
	George Siberry
Zhen Fu	
<b>FDA</b>	Ilona Bebenek, Tanvir Bell, Debra Birnkrant, Sarah Connelly, Ed Cox, Damon Deming, Robin Levis, Dionne Price, Dorothy Scott, Skip Nelson, Thamban Valappil