

**Food And Drug Administration  
Center For Biologics Evaluation And Research  
Vaccines And Related Biological Products Advisory Committee Meeting  
Wednesday, December 14 - 15, 2005  
Holiday Inn Select, 8120 Wisconsin Ave., Bethesda, MD 20814**

**AGENDA**

**Day 1**

**Open Session**

<b>9:00 a.m.</b>	<b>Call to Order and Opening Remarks</b>	<b>Gary D. Overturf, M.D., Chair</b>
9:05	Presentation of Appreciation Plaques to Retiring Members	Norman W. Baylor, Ph.D., FDA
9:10	Administrative Matters	Christine Walsh, R.N., FDA

**Safety and Efficacy of Rotavirus Vaccine Manufactured by Merck**

9:20 a.m.	FDA Brief Introduction Presentation of Questions	Rosemary Tiernan, M.D., M.P.H., FDA
9:30	Sponsor Presentation	Mark Bagarazzi, M.D./ Penny Heaton, M.D., M.P.H. Merck Research Laboratories
10:30	Break	
10:45	FDA Presentation	Rosemary Tiernan, M.D., M.P.H., FDA Hector Izurieta, M.D., M.P.H., FDA
11:45	Lunch	
1:15 p.m.	Open Public Hearing	
1:45	FDA Presentation of Questions	Rosemary Tiernan, M.D., M.P.H., FDA
2:00	Committee Discussion of FDA Questions Committee Recommendations	
4:30 p.m.	Adjourn for the day	

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**Day 2**

**Open Session**

<b>9:00 a.m.</b>	<b>Call to Order and Opening Remarks</b>	<b>Gary D. Overturf, M.D., Chair</b>
9:05	Administrative Matters	Christine Walsh, R.N., FDA

**Safety and Efficacy of ZOSTAVAX (Zoster Vaccine Live [Oka/Merck] ) Manufactured by Merck**

9:20 a.m.	FDA Brief Introduction Presentation of Questions	Patricia Rohan, M.D., FDA
9:30	Sponsor Presentation	David Gutsch, M.D./ Jeffrey Silber, M.D. Merck Research Laboratories
10:45	Break	
11:00	FDA Presentation	Patricia Rohan, M.D., FDA
12 noon	Lunch	
1:30 p.m.	Open Public Hearing	
2:00	FDA Presentation of Questions	Patricia Rohan, M.D., FDA
2:15	Committee Discussion of FDA Questions Committee Recommendations	
4:30 p.m.	Adjourn meeting	