

FOOD AND DRUG ADMINISTRATION
Center for Biologics Evaluation and Research
102nd Meeting of the Blood Products Advisory Committee (BPAC)
Hilton Washington DC North/Gaithersburg, 620 Perry Parkway
Gaithersburg, Maryland
May 15-16, 2012

DRAFT AGENDA

8:30 a.m.	Call to Order and Opening Remarks Introduction of Committee	F. Blaine Hollinger, M.D. Chair, BPAC
	Conflict of Interest Statement	Bryan Emery, LCDR Designated Federal Officer, BPAC
Topic I: Evaluation of the Safety and Effectiveness of the OraQuick® In-Home HIV Test, OraSure Technologies, Inc. (Device Panel)		
8:40 a.m.	Introduction	Hilary Hoffman (20'') DETTD, OBRR, FDA
9:00 a.m.	Orasure Presentation of OraQuick® In-Home HIV Test	(60'')
10:00 a.m.	FDA Risk Analysis of the OraQuick® In-Home HIV Test Based on Clinical Trial Performance	Richard Forshee, Ph.D. (35'') OBE, FDA
10:35 a.m.	Questions for Speakers	(20'')
10:55 a.m.	Break	(15'')
11:10 a.m.	Public Health Implications for a Home-Use HIV Test	Amy Lansky, MPH, Ph.D. (35'') Division of HIV/AIDS Prevention, CDC
11:45 a.m.	FDA Experience with Currently Marketed Home-Use Test Kits	Arleen Pinkos (20'') OIVD, CDRH, FDA
12:05 a.m.	Summary of FDA Analysis of the OraQuick® In-Home HIV Test and Questions for the Committee	Elliot Cowan, Ph.D. (20'') DETTD, OBRR, FDA
12:25 p.m.	Questions for Speakers	(20'')
12:45 p.m.	Lunch	
1:45 p.m.	Open Public Hearing	(1'45'')
3:30 p.m.	Break	(15'')

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10:40 a.m.	Impact of Overnight Hold of Whole Blood on Plasma Protein Function	Dana Devine, Ph.D. (20'') Canadian Blood Services Vancouver, BC Canada
11:00 a.m.	Considerations for Clinical Trials	Nisha Jain, M.D. (15'') DH, OBRR, FDA
11:15 a.m.	Questions for Speakers	(10'')
11:25 a.m.	Summary and Questions for the Committee	Ping He, M.D., FDA (10'')
11:35 a.m.	Lunch	
12:35 p.m.	Open Public Hearing	(85'')
2:00 p.m.	Open Committee Discussion Questions for the Committee	(1'15'')
3:15 p.m.	Break	(15'')
Committee Updates		
3:30 p.m.	Update on HHS Activities Related to the Evaluation of the Donor Deferral Policy for Men Who Have Had Sex with Other Men (MSM)	James Berger (20') Office of the Assistant Secretary of Health, HHS
3:50 p.m.	Questions	(5'')
4:00 p.m.	Adjourn for the Day	