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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3:45 p.m.	Open Committee Discussion	(1'15")
	Questions for the Committee	

5:00 p.m. Adjourn for the Day

Wednesday, May 16, 2012 DAY 2

8:00 a.m. Call to Order and Opening Remarks F. Blaine Hollinger, M.D.

Introduction of Committee Chair, BPAC

Conflict of Interest Statement Bryan Emery, LCDR

Designated Federal Officer,

BPAC

Topic II: Evaluation of Possible New Plasma Products Following In-Process Storage at Room Temperature for up to 24 Hours

8:10 a.m.	Introduction and FDA Perspective	Ping He, M.D. (40") DH, OBRR, FDA
8:50 a.m.	Statistical Considerations in Trial Design	John Scott, Ph.D., OBE, FDA (10')
9:00 a.m.	Thromboembolic Risks of Patients with Inherited or Acquired Low Protein S Levels	Deborah Ornstein, M.D. (20") Dartmouth-Hitchcock Medical Center
9:20 a.m.	Causes of Low Protein S Levels in Therapeutic Plasma: Clinical Significance	Peter Hellstern, M.D. (30") Institute of Hemostaseology and Transfusion Medicine, Academic City Hospital Ludwigshafen, Germany
9:50 a.m.	Presentation of the BEST Study and UK Data	Rebecca Cardigan, Ph.D. (20") National Blood Service, UK
10:10 a.m.	Questions for Speakers	(15")
10:25 a.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			