

FOOD AND DRUG ADMINISTRATION

Center for Biologics Evaluation and Research
121st Meeting of the Blood Products Advisory Committee
Tommy Douglas Conference Center
New Hampshire Avenue
Silver Spring, MD 20903

DRAFT AGENDA

November 22, 2019

8:30 a.m.	Call to Order and Opening Remarks Introduction of Committee	Richard Kaufman, M.D. Chair
8:40 a.m.	Conflict of Interest Statement	Christine Vert, M.S. Designated Federal Officer
Topic I:	Considerations for Cold Stored Platelet Products Intended for Transfusion	
8:45 a.m.	Introduction to the Topic	Carlos Villa, M.D., Ph.D. OBRR, FDA (15')
9:00 a.m.	Platelet Transfusion in Clinical Medicine	Darrell Triulzi, M.D. University of Pittsburgh (30')
9:30 a.m.	Introduction to <i>in vitro</i> Characterization of Platelets and Regulatory Approaches to Evaluation of Platelet Products	Monique Gelderman, Ph.D. OBRR, FDA (20')
9:50 a.m.	<i>In vitro</i> , preclinical, and <i>in vivo</i> Recovery and Survival Studies of Cold Stored Platelets	Moritz Stolla, M.D., Ph.D. Bloodworks Northwest (25')
10:15 a.m.	Questions for Speakers	(10')
10:25 a.m.	Break	(15')
10:40 a.m.	Clinical Trial of Cold Stored Platelets in Cardiac Surgery	Geir Strandenes, M.D. Norwegian Armed Forces Medical Services (30')
11:10 am	Blood Establishment Considerations for Cold Stored Platelets	James Stubbs, M.D. Mayo Clinic (25')
11:35 am	Role of Cold Stored Platelets in Clinical Care in the General Population	Donald Jenkins, M.D. University of Texas San Antonio Health (25')
12:00 p.m.	Questions for the Speakers	(10')
12:10 p.m.	Lunch	(60')
11/5/19		

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1:10 p.m.	Evaluation of Cold Stored Platelet Function and Military Experience with Cold Stored Platelets	COL Andrew Cap, M.D., Ph.D. U.S. Army Institute for Surgical Research (30')
1:40 p.m.	A Proposed Clinical Trial to Evaluate the Efficacy of Cold Stored Platelets in Surgical Patients and Potential Endpoints for Cold Stored Platelets Clinical Studies	Philip Spinella, M.D. Washington University (30')
2:10 p.m.	Questions for Speakers	(10')
2:20 p.m.	Break	(15')
2:35 p.m.	Open Public Hearing	(60')
3:35 p.m.	Open Committee Discussion Questions for the Committee	(70')
4:45 p.m.	Adjournment	