

# FOOD AND DRUG ADMINISTRATION

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

Meeting Webcast Link: <https://www.ustream.tv/channel/Y3bDz3eBTFb>

## DRAFT AGENDA 2

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	Christina Vert, M.S. Designated Federal Officer
<b>Topic I:</b>	<b>Considerations for Cold Stored Platelet Products Intended for Transfusion</b>	
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 (35')
9:35 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')
9:55 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')
10:20 a.m.	Questions for Speakers	(10')
10:30 a.m.	Break	(15')
10:45 a.m.	Clinical Trial of Cold Stored Platelets in Cardiac Surgery	Geir Strandenes, M.D. Norwegian Armed Forces Medical Services (30')
11:15 am	Blood Establishment Considerations for Cold Stored Platelets	James Stubbs, M.D. Mayo Clinic (25')
11:40 am	Role of Cold Stored Platelets in Clinical Care in the General Population	Donald Jenkins, M.D. University of Texas San Antonio Health (25')
12:05 p.m.	Questions for the Speakers	(10')
12:15 p.m.	Lunch	(60')

11/15/19

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1:15 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')
1:45 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')
2:15 p.m.	Questions for Speakers	(10')
2:25 p.m.	Break	(15')
2:40 p.m.	Open Public Hearing	(60')
3:40 p.m.	Open Committee Discussion Questions for the Committee	(70')
4:50 p.m.	Adjournment	