FOOD AND DRUG ADMINISTRATION (FDA)

Center for Biologics Evaluation and Research (CBER)
125th Meeting of the Blood Products Advisory Committee (BPAC)
May 9, 2024

<u>Meeting Information</u> <u>Briefing Document</u> <u>AABB Joint Statement</u>

Event Materials Discussion Questions

Meeting Transcript AABB Summary in Weekly Report

Topic: The committee met in open session to discuss strategies to reduce the risk of transfusion-transmitted malaria by testing blood donations from donors at risk of malaria exposure.

EDT Time	Presentation/Presenter
9:30 a.m.	Opening Remarks: Call to Order and Welcome (5 min.)
	 Zbigniew "Ziggy" Szczepiorkowski, M.D., Ph.D., F.C.A.P. Chair, BPAC Professor of Pathology and Laboratory Medicine, Professor of Medicine Dartmouth's Geisel School of Medicine
	Administrative Announcements, Roll Call, and Conflict of Interest Statement (15 min.)
	Christina Vert, M.S., Designated Federal Officer, BPAC Division of Scientific Advisors and Consultants (DSAC) Center for Biologics Evaluation and Research (CBER), FDA
9:50 a.m.	Introduction (50 min.)
	Introduction and Charge to the Committee (15 min.)
	 Anne Eder, M.D., Ph.D. Director, Office of Blood Research and Review (OBRR) Center for Biologics Evaluation and Research (CBER), FDA
	Public Health and Clinical Malaria in the U.S. (25 min.)
	Seymour Williams, M.D., M.P.H. Team Lead for the Domestic Response Team Domestic Malaria Team, Malaria Branch Division of Parasitic Diseases and Malaria National Center for Emerging and Zoonotic Infectious Diseases US Centers for Disease Control and Prevention

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	OSA (10 min) Pofor to the Meeting Transcript
	Q&A (10 min.) Refer to the Meeting Transcript.
10:50 a.m.	<u>Transfusion-Transmitted Malaria in the United States</u> (25 min.)
	Sanjai Kumar, Ph.D.
	Chief, Laboratory of Emerging Pathogens (LEP)
	Division of Emerging and Transfusion Transmitted Diseases (DETTD)
	Office of Blood Research and Review (OBRR), CBER,
	FDA
	Q&A (10 min.)
	QaA (10 IIIIII.)
11:25 a.m.	Molecular testing for detection of asymptomatic Plasmodium
	infections (25 min.)
	- Sugar Calal M.D.
	 Susan Galel, M.D. Global Senior Director of Medical Affairs, Donor Screening
	Roche Diagnostics Solutions
	Q&A (10 min.)
12:00 p.m.	FDA Policy Considerations for Testing Blood Donations for Malaria
	Infection (25 min.)
	I II O I I M D II
	 Jennifer Scharpf, M.P.H. Associate Director for Policy
	Office of Blood Research and Review (OBRR), CBER, FDA
	Q&A (10 min.)
1:00 p.m.	Open Public Hearing (30 min.)
1.00 p.m.	AABB Joint Statement
1:30 p.m.	Open Committee Discussion and Recommendations (77 min.)
2:47 p.m.	Adjourn Meeting
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	 Christina Vert, M.S., Designated Federal Officer, BPAC DSAC, CBER, FDA
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