

FOOD AND DRUG ADMINISTRATION (FDA)
Center for Biologics Evaluation and Research (CBER)
125th Meeting of the Blood Products Advisory Committee (BPAC)
May 9, 2024
Via Web Conference
Draft AGENDA

Topic: The committee will meet 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.

AGENDA – OPEN SESSION

EST Time	Presentation/Presenter
9:30 a.m.	<p><u>Opening Remarks: Call to Order and Welcome (5 min.)</u></p> <ul style="list-style-type: none"> • 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 <p><u>Administrative Announcements, Roll Call, and Conflict of Interest Statement (15 min.)</u></p> <ul style="list-style-type: none"> • 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.	<p><u>Introduction (40 min.)</u></p> <p>Opening Remarks and Charge to the Committee (5 min.)</p> <ul style="list-style-type: none"> • Anne Eder, M.D., Ph.D. Director, Office of Blood Research and Review (OBRR) Center for Biologics Evaluation and Research (CBER), FDA <p>Public Health and Clinical Malaria in the U.S. (25 min.)</p> <ul style="list-style-type: none"> • 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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	Q&A (10 min.)
10:30 a.m.	BREAK (15 min.)
10:45 a.m.	<p><u>Transfusion-Transmitted Malaria in the United States (25 min.)</u></p> <ul style="list-style-type: none"> • 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 <p>Q&A (10 min.)</p>
11:20 a.m.	<p><u>Molecular testing for detection of asymptomatic <i>Plasmodium</i> infections (25 min.)</u></p> <ul style="list-style-type: none"> • Susan Galel, M.D. Global Senior Director of Medical Affairs, Donor Screening Roche Diagnostics Solutions <p>Q&A (10 min.)</p>
11:55 p.m.	<p><u>FDA's Policy Considerations for Testing Blood Donations for Malaria Infection (25 min.)</u></p> <ul style="list-style-type: none"> • Jennifer Scharpf, M.P.H. Associate Director for Policy Office of Blood Research and Review (OBRR), CBER, FDA <p>Q&A (10 min.)</p>
12:30 p.m.	<u>LUNCH BREAK (30 min.)</u>
1:00 p.m.	<u>Open Public Hearing (60 min.)</u>

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2:00 p.m.	<u>Break (10 min.)</u>
2:10 p.m.	<u>Open Committee Discussion and Recommendations (60 min.)</u>
3:10 p.m.	<u>Adjourn Meeting</u> <ul style="list-style-type: none">• Christina Vert, M.S., Designated Federal Officer, BPAC DSAC, CBER, FDA