

FOOD AND DRUG ADMINISTRATION
Center for Biologics Evaluation and Research
124th Meeting of the Blood Products Advisory Committee
April 26, 2023
Via Web Conference
DRAFT AGENDA

Topic: Overview of the Research Programs in the Division of Hemostasis, Office of Plasma Protein Therapeutics Chemistry, Manufacturing, and Controls, Office of Therapeutic Products (OTP), Center for Biologics Evaluation and Research (CBER)

AGENDA – OPEN SESSION

| EST Time | Presentation/ Presenter |
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| 9:30 a.m. | <p>Opening Remarks: Call to Order and Welcome (5 min.) Zbigniew “Ziggy” Szczepiorkowski, MD, PhD, FCAP, Chair, BPAC Professor of Pathology and Laboratory Medicine, Professor of Medicine Dartmouth’s Geisel School of Medicine</p> <p>Administrative Announcements, Roll Call, and Conflict of Interest Statement (15 min.) Christina Vert, M.S., Designated Federal Officer, BPAC DSAC, CBER, FDA</p> |
| 9:50 a.m. | <p>Overview of CBER Research Programs (10 min.) Karen Elkins, Ph.D., Associate Director for Science, Office of the Director, CBER, FDA</p> <p>Q & A (5 min.)</p> |
| 10:05 a.m. | <p>Overview of OTP and Office of Plasma Protein Therapeutics Chemistry, Manufacturing, and Controls Research Programs (20 min.) Basil Golding Ph.D., Acting Director, Office of Plasma Protein Therapeutics Chemistry, Manufacturing, and Controls, OTP, CBER</p> <p>Q & A (5 min.)</p> |
| 10:30 a.m. | <p>Overview of Division of Hemostasis Research Programs (20 min.) Chava Kimchi-Sarfaty, Ph.D., Deputy Associate Director for Research, OTP, CBER</p> <p>Q & A (5 min.)</p> |
| 10:55 a.m. | <p>BREAK (10 min.)</p> |

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| 11:05 a.m. | Open Public Hearing (60 min.) |
| 12:05 p.m. | Closed Session Committee Discussion, Voting, and Recommendations (55 min.) |
| 1:00 p.m. | Adjourn Meeting Christina Vert, M.S., Designated Federal Officer, BPAC DSAC, CBER, FDA |