



# Lupus **PFDD** Meeting

Monday, September 25, 2017

10:00 a.m. – 4:15 p.m.

College Park Marriott Hotel & Conference Center

Potomac Ballroom

Hyattsville, Maryland

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| 9:00 – 10:00 a.m.       | <b>Registration</b>  |
| 10:00 a.m.              | <b>Welcome</b><br>James Valentine, Moderator   |
| 10:00 – 10:15 a.m.      | <b>Opening Remarks</b><br>Kathleen A. Arntsen<br>Lupus Community Representative  |
| 10:15 – 10:25 a.m.      | <b>Overview of FDA's PFDD Initiative and Road to Clinical Trial Endpoints</b><br>Pujita Vaidya, MPH<br>Acting Director, Decision Support and Analysis Team, Office of Strategic Programs, Food and Drug Administration Center for Drug Evaluation and Research |
| 10:25 – 10:40 a.m.      | <b>FDA Insights on PFDD Initiative and Lupus</b><br>Janet Woodcock, MD<br>Director, Food and Drug Administration Center for Drug Evaluation and Research<br>Debra Lappin, Facilitator  |
| 10:40 – 10:55 a.m.      | <b>Overview of Lupus and Available Treatments</b><br>Anca D. Askanase, MD, MPH<br>Associate Professor of Medicine and Director, Lupus Center, Columbia University Medical Center   |
| 10:55 – 11:05 a.m.      | <b>Overview of Discussion Format</b><br>James Valentine, Moderator   |
| 11:05 – 11:50 a.m.      | <b>Panel on Discussion Topic 1: Patient Perspectives on Disease Symptoms and Daily Impacts that Matter Most</b><br>Panelists<br>James Valentine, Moderator   |
| 11:50 a.m. – 12:50 p.m. | <b>Facilitated Discussion Topic 1</b><br>Persons with lupus and their representatives<br>James Valentine, Moderator  |

- 12:50 p.m. – 1:50 p.m.**      **Lunch**  
(In Chesapeake Salon C across from the Potomac Ballroom)
- 1:50 – 1:55 p.m.**      **Afternoon Welcome**  
James Valentine, Moderator
- 1:55 – 2:40 p.m.**      **Panel on Discussion Topic 2: Patient Perspectives on Current Approaches to Treating Lupus**  
Panelists  
James Valentine, Moderator
- 2:40 – 3:40 p.m.**      **Facilitated Discussion Topic 2**  
Persons with lupus and their representatives  
James Valentine, Moderator
- 3:40 – 3:55 p.m.**      **Open Public Comment Period**
- 3:55 – 4:10 p.m.**      **Summary Remarks**  
Nikolay P. Nikolov, MD  
Clinical Team Leader, Division of Pulmonary, Allergy, and Rheumatology  
Products, Food and Drug Administration
- 4:10 – 4:15 p.m.**      **Closing Remarks**  
James Valentine, Moderator