

AGENDA

Public Meeting on Financial Transparency and Efficiency of the Prescription Drug User Fee Act, Biosimilar User Fee Act, and Generic Drug User Fee Amendments

June 7, 2019

9:00 am – 11:30 am

White Oak, Great Room
Section A (1503A)

- 8:00 am – 9:00 am** **Registration and Check-In Tables Open**
- 9:00 am** **Meeting Begins**
Monica Ellerbe, Director of Business Management Services
Office of Finance, Budget and Acquisitions
- 9:05 am – 9:10 am** **Welcome and Introduction**
Patrizia Cavazzoni, M.D., Deputy Director for Operations
Office of the Center Director | CDER
- 9:10 am – 9:40 am** **General Overview of 5-Year Financial Plans**
David Miller, Director of Division of User Fees
Office of Finance, Budget and Acquisitions
- 9:40 am – 10:20 am** **Resource Capacity Planning (RCP) and Modernized Time Reporting (MTR) Implementation Progress**
Andrew Kish, Director
Office of Program and Strategic Analysis | CDER
Josh Barton, Director of Resource Capacity Planning Team
Office of Program and Strategic Analysis | CDER
- 10:20 am – 10:30 am** **Break**
- 10:30 am – 10:50 am** **Financial Management Evaluation for Human Drug User Fees**
Jim Taylor
Grant Thornton, LLP – Health FFRDC
- 10:50 am – 11:10 am** **FDA Response to Financial Management Evaluation**
Jay Tyler, Chief Financial Officer
Office of Finance, Budget and Acquisitions
- 11:10 am – 11:30 am** **Open Public Comment**
Monica Ellerbe, Director of Business Management Services
Office of Finance, Budget and Acquisitions