

## Financial Incentives for CDER Medical Products

**June 10, 2019 from 10:00 a.m. to 3:00 p.m. Eastern**

10.00 a.m.	Webinar Overview	CDER Small Business and Industry Assistance (SBIA)
10:05	<b>Prescription Drug User Fee Act Waivers, Exemptions, and Refunds -Oh My</b>	<b>Jeen Min, RPh</b> <i>Commander, US Public Health Service Branch Chief</i> Division of User Fee Management & Budget Formulation (DUFMBF) Office of Management (OM) CDER   FDA
11:05	<b>Navigating the World of Biosimilar User Fees</b>	<b>Beena Alex, MPH, MBA</b> <i>Lead Management Analyst</i> DUFMBF   OM   CDER   FDA
11:25	Break	
11:30	Questions and Answers	Jeen Min Beena Alex
11:50	Lunch Break	
12:10	<b>Exclusivity –Which one is for me?</b>	<b>Rinku Patel, PharmD</b> <i>Lieutenant Commander, US Public Health Service</i> Division of Legal and Regulatory Support (DLRS) Office of Generic Drug Policy (OGDP) Office of Generic Drugs (OGD)   CDER   FDA
1:10	Break	
1:15	Questions and Answers	Rinku Patel
1:25	<b>Priority Review Vouchers – Redemption and General Information</b>	<b>Peter Chen, RPh, ExecJD</b> <i>Commander, US Public Health Service</i> DUFMBF   OM   CDER   FDA
1:55	<b>Orphan Drugs Program</b>	<b>Roberta Szydlo, RPh, MBA, RAC, BCGP</b> <i>Captain, US Public Health Service Program Management Officer</i> Office of Orphan Products Development (OOPD) Office of Clinical Policy and Programs   FDA
2:40	Break	
2:45	Questions and Answers	Peter Chen Roberta Szydlo
3:00	Closing Remarks	CDER Small Business and Industry Assistance (SBIA)