Prescription Drug User Fee Act (PDUFA) 201 Briefing

September 2, 2015
12:00 – 1:30 PM

PhRMA
950 F Street, NW, Suite 300

Please join BIO and PhRMA for a second discussion focusing on the reauthorization of the Prescription Drug User Fee Act (PDUFA) for fiscal years 2018 through 2022. The goal of PDUFA is to supplement congressional appropriations so that FDA can hire staff, improve systems, and establish a better managed human drug review process to make important therapies available to patients sooner without compromising review quality or FDA's high standards for safety, efficacy, and quality.

Through greater predictability and transparency in the drug and biologic review process over the last 20 years, PDUFA has resulted in timelier patient access to more than 1,500 new medicines and biologics. The current authorization of the program (PDUFA V) expires in September 2017. The PDUFA VI reauthorization process began on July 15, 2015 with the first in a series of FDA public meetings intended to solicit stakeholder input on FDA's drug review program in advance of PDUFA VI negotiations.

Please join for us for a discussion of next steps in the PDUFA reauthorization process, including PDUFA VI priorities for the patient community and the biopharmaceutical industry.

Confirmed Speakers

- Cynthia Bens, Vice President, Public Policy, Alliance for Aging Research
- Maureen Japha, JD, Associate Director, Intellectual Property, FasterCures
- Sascha Haverfield, PhD, Vice President for Scientific and Regulatory Affairs, PhRMA
- Kay Holcombe, Senior Vice President, Science Policy, BIO

Lunch will be served. If you have any questions, please contact Gautami Inamdar.
To RSVP for the briefing, please click here.