PDUFA - History

- The Prescription Drug User Fee Act (PDUFA) was created by Congress in 1992 and authorizes FDA to collect fees from sponsors at the time a New Drug Application (NDA) or Biologics License Application (BLA) is submitted
- A major PDUFA goal is for the FDA to review and provide a ruling on applications **within one year**
- PDUFA must be **reauthorized every five years**, and was renewed in 1997 (PDUFA II), 2002 (PDUFA III), 2007 (PDUFA IV), and 2012 (PDUFA V) and 2017 (PDUFA VI)
- In order to continue collecting such fees, the FDA is required to meet certain performance benchmarks, primarily related to the speed of certain activities within the NDA review process