Exploring the Link between the FDA Approval Process and the Patenting of Drugs and Biologics

Location

Webinar

Date & Time

Start Date: 10/13/2022
Start Time: 1:00 pm
End Time: 2:15 pm EDT

Keri Schaubert will present at the 2nd Annual Passport to Proficiency on the Essentials of Hatch-Waxman and BPCIA Conference. Keri will join a panel discussing identifying the application process for the approval of a new drug, i.e., small molecule, new chemical entities, etc.

Rx Drugs (new drugs)

- NDA (New Drug Application): definition, contents and regulatory overview
- INDA (Investigational New Drug Application) aka "IND"
  - How does it differ from an NDA?
- Accelerated approvals
  - Defining eligibility criteria for accelerated approval and priority reviews
  - What portions of approval submissions might FDA release and when?
- Using advisory committees in the approval process

Biologics

- How does the approval process for a biologic differ from that of a drug?
- BLA (Biological Licensing Application): application and filing
  - How does a biologic differ from a drug?
  - Which products require BLAs instead of NDAs?
- Why is it a "license," rather than an "approved application"?

Sponsor

American Conference Institute

ATTORNEYS

Keri L. Schaubert, Ph.D.
Member
kschaubert@cozen.com
(212) 883-2258

RELATED PRACTICES

Hatch-Waxman & Biologics
Intellectual Property
Patents

COZEN O'CONNOR

LEARN MORE

CLE Programs

Subscribe To Publications

Contact