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

Location

Webinar

Date & Time

Start Date: 10/07/2021
Start Time: 1:00 pm
End Time: 5:00 pm EDT

Aaron Lukas will be presenting at the Hatch-Waxman and BPCIA Essentials program. This is a three week program on IP basics and regulatory fundamentals relative to small molecules and biologics for brand names, generics, and biopharmas. Aaron will be discussing the following:

Rx Drugs (new drugs)

- Identifying the application process for the approval of a new drug, i.e., small molecule, new chemical entities, etc.
- 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"?

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ATTORNEYS

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