FDAnews Announces — Expediting the Generic Drug Approval Process: FDA’s New Initiatives on Drug Competition Webinar, Dec. 6, 2018

A record number of generic drugs were approved this year! Here’s how to expedite a generic drug application.

**An FDAnews Webinar**
Dec. 6, 2018 — 1:30 p.m. – 3:00 p.m. ET

A record number of generic drugs have been approved this year.

In August the FDA approved the first generic drug, potassium chloride oral solution, under a new approval pathway created to expedite the development and review of a generic sole source drug.

With the new expediting process, Commissioner Gottlieb believes that record highs will be achieved year on year.

In 90 fast-paced minutes attorneys Chad Landmon and Suchira Ghosh of Axinn, Veltrop & Harkrider LLP will methodically lay out the various policies, how they’ve been implemented, how generic drug manufacturers can engage with them and identify possible issues. Attendees will learn the following:

- The new pathways to expedite approval of generic drug applications, including 180-day exclusivity
- Best practices to obtain exclusivity and the top don’ts for losing exclusivity
- Recent FDA policy statements and guidance on generic drugs and their impact on regulatory and quality professionals
- Substantive changes to REMS standards that impact ANDAs
- FDA’s other policy initiatives: prioritizing generic drug review; spur generic approvals to increase competition and lower cost, while maintaining quality
- How the real cost saving benefit provided by generics doesn’t come into full effect until there are multiple generic versions available

Register today to gain a clearer understanding of the various FDA initiatives surrounding generic drug access and how to best navigate these changes.

Meet the Presenters:
Chad Landmon, Partner, Axinn, Veltrop & Harkrider LLP
Chad Landmon is a Partner and chairs the FDA and IP practice groups at Axinn, Veltrop & Harkrider LLP. He has extensive experience assisting pharmaceutical companies with bringing their products to market, including navigating the complex drug approval pathway at FDA. Chad’s experience with FDA matters also includes litigation and advocacy surrounding generic drug marketing exclusivities and application approval standards.

Suchira Ghosh, Counsel, Axinn, Veltrop & Harkrider LLP
Suchira Ghosh is Counsel in the FDA and IP practice groups at Axinn. She has considerable experience with
FDA’s drug approval pathway and its various scientific, regulatory and legal challenges. She provides counseling related to FDA matters such as REMS, approval standards, and administrative dispute resolution.

Who Will Benefit:
- Regulatory Counsel
- Regulatory Affairs
- Safety and Pharmacovigilance
- REMS manager
- Legislative and Policy

Webinar Details:
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