

# Introduction to the 2024-2025 Edition

*Generic Pharmaceutical Patent and FDA Law* covers Food and Drug Administration (FDA) approval of generic drugs and the interaction of patents and FDA law. A practitioner's guide, it walks the reader through the stages of drug approval, identifying the critical issues in the process and advising the client about the issues and areas of concern or exploitation. It also discusses the areas that impact the interaction of patents and Food and Drug Administration law, including litigation.

Changes in this update includes:

- Revised and restructured Chapter 13 on Genus and Species;
- New entry in Section 101 cases detailing the decision in *ChromaDex Inc. v. Elysium Health, Inc.* [see § 5:15];
- New section on the Orange Book and delisting patents under the OB Transparency Act [see § 22:13];
- New section on citizen petitions based on confidential information from ANDA, specifically addressing protective orders and prohibited uses [see § 38:8];
- New section on ANDA considerations for 180-day exclusivity in Rx to OTC switches [see § 37:5];

The Publisher  
September, 2024