Introduction to the 2020 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:

- new section on the genus-species distinction in the written description defense [see § 4:12];
- new sections covering § 101 cases involving diagnostics versus method claims [see §§ 5:16-5:18];
- a new chapter on issues relating to the size/shape/color of generic products [see Chapter 35];
- a new chapter on pharmaceutical compounding [see Chapter 36];
- a new chapter on over the counter drugs [see Chapter 37].

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