



Patent Resources Group

Fundamental Building Blocks for Creating and Enforcing the FDA Orange Book Listable U.S. Patent Syllabus

Statutory and Regulatory Framework

FDA Form 3542a: General Information

The Drug Substance: How to List and Issues to Consider

The Drug Product: How to List and Issues to Consider

Methods of Use and the Use Code

Related Aspects of Hatch-Waxman: Non-patent Exclusivities and Patent Term Extensions

Putting It All Together