

GENERIC DRUGS, FDA, AND INTELLECTUAL PROPERTY LAW

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Syllabus

- I. Evolution of the U.S. Pharmaceutical Industry and Its Regulation By FDA – The Effects of the Federal Patent and Trademark Laws
- II. Summary Overview of FDA’s Product Approval Processes
 - A. The New Drug Approval Process
 - B. The Generic Drug Approval Process
 - C. The Biologics Approval Process
- III. Special Innovation Incentives and Disincentives for FDA-Regulated Products
 - A. Approval of Duplicates and Variants Based On Innovator Data – ANDAs, “Hybrid” NDAs, Follow-on Medical Devices, Follow-on Biologics
 - B. Infringement Safe Harbor for FDA Submission-Related Acts
 - C. Patent Term Extensions
 - D. Non-Patent Exclusive Marketing Rights - Orphan Drugs, New Compounds and Uses, Pediatric Studies
- IV. Eligibility for Abbreviated NDA Approval
 - A. The “Same”-ness Requirement – Active and Inactive Ingredients, Bioavailability, Conditions of Use, and Labeling
 - B. Approval Based On Discontinued Innovator Drug
- V. The Role of Patents in the FDA Approval Process
 - A. The Patent Listing (“Orange Book”) Requirement
 - B. The “Paragraph IV” Certification and Notice Requirement
 - C. ANDA Filing As An Act of Infringement
 - D. The Automatic 30-Month Stay of ANDA Approval
 - E. 180-Day Exclusivity For First Paragraph IV Filers
 - F. Antitrust Issues in Pharmaceutical Patent Litigation Settlements
- VI. The Impact of FDA Regulation on Copyright, Trademark, and Trade Dress Rights
 - A. Copyrighted Innovator Labeling and the Generic “Same Labeling” Requirement
 - B. Unapproved Products and the “Lawful Use in Commerce” Requirement
 - C. Statutory Product Categories and Likelihood of Confusion
 - D. FDA Regulation of Trademark Selection
 - E. Trade Dress Protection for Drug Product Color, Shape, and Size
 - F. Marketing Claims for FDA-Regulated Products
- VII. The Impact of FDA Regulation on Trade Secrets and Data Confidentiality