

Cut Drug Approval Time with a 505(b)(2)

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Appendices <i>(can be found on the CD in the back of this report)</i>	
A. Applications Covered by Section 505(b)(2) (FDA Draft Guidance)	
B. Approved Drug Products with Therapeutic Equivalence Evaluations 34 th Edition (Orange Book)	
C. New Chemical Entity Exclusivity Determinations for Certain Fixed-Combination Drug Products (FDA Draft Guidance)	
D. FDA Guidance for Industry: Codevelopment of Two or More New Investigational Drugs for Use in Combination	
E. Listed Drugs, 30-Month Stays, and Approval of ANDAs and 505(b)(2) Applications Under Hatch-Waxman, as Amended by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (FDA Draft Guidance)	