

Expediting the FDA Generic Drug Approval Process

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Appendices (can be found on the CD in the back of this report)

- A. ANDA Submissions – Content and Format of Abbreviated New Drug Applications (FDA draft guidance)

- B. ANDA Submissions – Refuse-to-Receive Standards (FDA guidance)
- C. Bioequivalence Studies with Pharmacokinetic Endpoints for Drugs Submitted Under an ANDA (FDA draft guidance)
- D. Submission of Summary Bioequivalence Data for ANDAs (FDA guidance)
- E. ANDAs: Stability Testing of Drug Substances and Products, Questions and Answers (FDA guidance)
- F. ANDA Filing Checklist
- G. ANDA Submissions – Amendments and Easily Correctable Deficiencies Under GDUFA (FDA draft guidance)