this approach must have a substantial degree of confidence in the robustness of their methods. Otherwise, late fixes may be required and the ANDA submission will have to be amended.

CONCLUSION

As the information in this chapter demonstrates, QA and QC oversight is an essential part of generic drug development. Firms that establish and follow sound procedures and practices for drug development and ensure proper quality oversight throughout the process will reap the benefits of successful PAIs and timely ANDA approvals. Although resource intensive, this approach can provide substantial commercial advantage and significant contribution to the "bottom line."

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REFERENCES

1. Berman, J., Planchard, J. (1995). A blend uniformity and unit dose sampling. *Drug Development and Industrial Pharmacy, 21*, 1257–1283.
2. Berman, J., Schoeneman, A., Shelton, J. T. (1996). Unit dose sampling: A tale of two thieves. *Drug Development and Industrial Pharmacy, 22*, 1121–1132.
3. *FDA's Guide to Inspections of Oral Solid Dosage Forms*, January 1994.
4. Technical Report No. 25: Blend uniformity analysis: validation and in-process testing (1997). *Journal of Pharmaceutical Science and Technology, 51*, 51–599. Supplement published by the Parenteral Drug Association and the FDA's response to it, 8/29/97 (by Pat Beers Block, Special Assistant to the Director, Division of Manufacturing and Product Quality, Office of Compliance, CDER).
5. *Manual of Policies and Procedures 5223.3* (formerly Office of Generic Drugs Policy and Procedure Guide 22-90), Center for Drug Evaluation and Research, Food and Drug Administration.
6. The Pharmacy Times Web Site Top 200 list at www.pharmacytimes.com.
7. SUPAC-IR: Immediate-Release Solid Oral Dosage Forms: Scale-Up and Post-Approval Changes: Chemistry, Manufacturing and Controls, In Vitro Dissolution Testing and In Vivo Bioequivalence Documentation; Center for Drug Evaluation and Research, Food and Drug Administration, November 1995. Other SUPAC documents are available on the FDA Web site: http://www.fda.gov/cder/guidance/index.htm.
8. Guidance for Industry, Changes to an Approved NDA or ANDA, Center for Drug Evaluation and Research, Food and Drug Administration, November 1999. Guidance for Industry, Changes to an Approved NDA or ANDA, Questions and Answers, Center for Drug Evaluation and Research, Food and Drug Administration, January 2001.
9. *United States of America v. Barr Laboratories, Inc. et al.,* Civil Action No. 92-1744, U.S. District Court for the District of New Jersey, February 4, 1993.