
13 Postapproval Changes and Postmarketing Reporting of Adverse Drug Experiences

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INTRODUCTION

Approval of an abbreviated new drug application (ANDA) is only the beginning of a generic drug product's history, as there are numerous postapproval requirements and activities to ensure that marketed drug products remain safe and effective. This chapter discusses a few of the important postapproval requirements from a regulatory affairs perspective.

Frequently, changes are made to the chemistry, manufacturing, and controls (CMC) section of an ANDA following approval and applicants are required to report these changes to the U.S. Food and Drug Administration (FDA). For example, an