Author Acknowledgments

RAPS and the lead editors, Linda McBride and Pallavi Trivedi, thank the following subject matter experts for sharing their experience and knowledge and volunteering their time to contribute to this first edition of Postapproval Changes for Drugs: A Practical Guide.

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SECTION I

Marketing Authorization Transfers, Renewals, and Administrative Changes

Chapter 1: United States

By Melodi McNeil, RPh, MS

Introduction

Globally, the term "marketing application" (MA) is applied to the collection of data, analyses, and summary reports ("the dossier") pharmaceutical applicants submit to regulators to support a formal request for commercial distribution of medicinal products. MAs contain evidence intended to demonstrate a medicinal product's safety, effectiveness, and quality and are subject to many technical, discipline-specific, and administrative regulatory requirements as a condition of approval.

Even after an MA is approved, there are regulatory requirements that continue to apply, e.g., when an MA is transferred from one applicant to another; annual updates; and other administrative changes in the elements that comprise the MA or that impact the MA overall. While it may be tempting to deprioritize or overlook compliance with the regulatory requirements that govern these changes, they serve an important function: facilitating the continuous medicinal product surveillance through which regulators support and maintain public health. Further, in some cases, noncompliance can be associated with significant adverse consequences, including proposed withdrawal of the MA or financial penalties.

This chapter reviews applicable US regulatory requirements for MA transfers and other administrative changes. The requirements that govern administrative changes to drug master files (DMFs) are also reviewed.

Key Terms

The US Food and Drug Administration (FDA) recognizes three broad categories of MAs for human drug/biologic products: the new drug application (NDA), the biologics license application (BLA), and the abbreviated new drug application (ANDA).

The term NDA describes the dossier applicants use to propose marketing of a new drug, i.e., one not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the condition prescribed, recommended, or suggested in the labeling.[1] The regulations having to do with NDAs are found in 21 CFR Part 314. The applicable statute is Section 505 of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

Similarly, a BLA is a request for permission to introduce, or deliver for introduction, a biologic product into interstate commerce. The BLA is regulated under 21 CFR Parts 600–680.[2] Biologics are regulated under Section 262 of the Public Health Service Act.