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Judy Bingham, MHA

Director
Easington Pty Ltd
Australia
Chapters 4 and 8

Juliane Carvalho, MS, RAC-Drugs

Lead Regulatory Health Project Manager
US Food and Drug Administration
US
Chapter 15

Hakima Hoesch, RAC-Drugs

Regulatory Affairs Senior Manager
Hikma Pharmaceuticals
Jordan
Chapter 5

David Jefferys, MD

Senior Vice President
Eisai
US
Preface

Dachelle Johnson, PharmD, RAC-US

AstraZeneca
Global Development Scientist Director
US
Chapter 20

Yingying Liu, MSc

Associate Director
CSL Behring
Switzerland
Chapter 12 and 17

Murphy Mao, MSc

Senior Regulatory Affair Manager
CSL Behring
China
Chapter 17

Linda McBride, RPh, RAC-US

Regulatory and Compliance Consultant
US
Preface, Chapters 9, and 11

Karin McIntosh, MPharm, RAC-Drugs

Vice President, Head of Regulatory Affairs
NexImmune Inc.
US
Chapters 7 and 16

Melodi McNeil, RPh, MS

Director, Regulatory Policy and Intelligence
AbbVie
US
Chapter 1

Moonmoon Mishra, MPharm

Senior Manager, Regulatory Affairs
Viatris Inc. (Erstwhile Mylan Pharmaceuticals Inc.)
India
Chapters 6 and 7

Faustin Ndindayino, PhD

CEO and Managing Director
Afrobridge Pharma Ltd.
Mali
Chapters 19 and 22

Hongbo Pan, MBA

Head of China RA and R&D Site (Shanghai
and Beijing)
CSL Behring
Chapter 17

Hadeer Abdulbasir Sayed

EMEA Regulatory Affairs Lifecycle Manager
Egypt
Chapters 13 and 14

**Kathrin Schalper, PhD, RAC-US, RAC-EU,
RAC-CAN, RAC-Devices**

Principal Consultant, Regulatory Affairs and
Managing Member
Senita Consulting, LLC
US
Chapter 10

Seema Singh, MSc

Group Leader Regulatory Affairs and CMC
Mitsubishi Tanabe Pharma Corp.
Japan
Chapter 9

Shakti Tripathy, MPharm

Regulatory Affairs
Dr. Reddy's Laboratories Ltd.
India
Chapter 2

Pallavi Trivedi, MPH, RAC-US

Senior Manager
Viartis
Chapters 3 and 21

Blaine Van Leuven, MS, RAC

Director, Regulatory CMC
Premier Consulting
US
Chapter 6

Julie Watchorn, MSc, RAC-EU

Senior Regulatory Affairs Consultant
Parexel
Ireland
Chapters 11 and 21

**Fatima Zaid Abu Zanat, MSc, RPh, RAC-
Drugs, RAC-Devices**

Regional Director of Regulatory Affairs and
Scientific Office
Middle East, Turkey, and Africa
Ispen
UAE
Chapter 18

Jing Zhou, MS

Manager, Regulatory CMC
PTC Therapeutics
US
Chapter 15

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.