

Mastering the FDA’s Import Rules

Table of Contents

Introduction

Think Like the FDA to Avoid and Manage Import Holds 4

How FDA Import Processes Work 4

How to Avoid – or Fight – Detentions and Refusals 7

Mastering PREDICT..... 9

Using FOIA to Your Advantage 12

Device Reclassification..... 12

Top Issues that Can Cause Import Holds 16

FDA Traceability Requirements 16

Other FDA Labeling Requirements 17

FDA Product Information Requirements 17

Importer Documentation Requirements 19

Inspection Refusals 20

Affirmation of Compliance Codes 20

The Scope of FDA Authority 22

Regulatory and Legal Authority 22

Appendices 26

- A. Medical Device Classification Procedures (FDA proposed rule)
- B. Drug Supply Chain Security Act (DSCSA)
- C. Food and Drug Administration Safety and Innovation Act (FDASIA)
- D. FDA Affirmation of Compliance (AofC) Codes
- E. FDA Affirmation of Compliance (AofC) Code Quick Reference
- F. 21 USC 381(a)