

Managing Product Pipeline Communications

Table of Contents

Introduction

Best Practices for Pipeline Communications..... 3

Other Preapproval Communications 4

FDA Enforcement Actions..... 5

Top 12 Tips for FDA Compliance..... 8

SEC Enforcement Actions..... 10

Disclosure Best Practices 14

Top Tips for Talking with Analysts and Investors..... 14

Managing Compliance Obligations 19

The FDA Is Watching..... 19

The SEC Is Watching, Too..... 20

Meeting SEC Disclosure Obligations in an FDA-compliant Manner 21

Appendices..... 24

A. 21 CFR 312.7

B. Responding to Unsolicited Requests for Off-Label Information About Prescription Drugs and Medical Devices (FDA draft guidance)

C. 21 USC 352

D. 21 CFR 812.7