

Table of Contents

Dr. Sharlin's Credentials.....	5
Outline Of This Presentation	6
Reasons Why FDA Created New Package Insert Requirements	7
Submission Types Covered by The New Regulations	8
Changes to Approved Drugs That Trigger The New Labeling Regulations	9
Phased Implementation of the New Requirements	10
List of Headings in Old and New Format.....	11
Factors to Consider When Converting From Old to New Format.....	12
Factors to Consider When Converting From Old to New Format (applicable regulations)	13
Important Changes Between Old and New Format.....	14
Mapping An Old Format Label To A New Format Label	15
How To Organize Information Among Sections In The New Format	16
“Highlights”: New Section, Overview	17
“Highlights” – New Section, Example	18
“Highlights” Section – Regulations & Sample Text.....	19
“Highlights” Section – Regulations & Sample Text (2)	20
“Highlights” Section – Regulations & Sample Text (3)	21

“Highlights” Section – Regulations & Sample Text (4)	22
“Contents”: New Section, Example	23
“Contents” Section: Regulations.....	24
Clinical Studies Section: Selecting Studies To Include/Exclude	25
Clinical Studies Section: Describing Studies.....	26
Clinical Studies Section: Describing Studies (2)	27
Clinical Studies Section: Describing Studies (3)	28
Clinical Studies Section: Describing Study Results.....	29
Clinical Studies Section: Describing Study Results (2)	30
Label Wording: Terms and Phrases to Avoid and Their Alternatives.....	31
Safety Information: Sections to Use in the New Label	32
Safety Information: Sections to Use in the New Label (2).....	33
Adverse Reactions Section	34
Generic Drug Labeling	35
Generic Drug Labeling, Excerpts From Final Rule and Guidances.....	36
How To Interpret a FDA Guidance	37
FDA Guidances About New Requirements	38
Information About New Package Insert Requirements On The FDA Web Site...	39
Model SOPs: Section Headings	40

Features of the Model SOPs	41
Required Activities For Each New SOP	42
SOP #1, Determining When A Label Must Be In The New (2006) Format.....	43
SOP #2, Format and Organization Requirements For The New(2006) Label.....	49
Summary of Audioconference; New Package Insert Requirements	61
Next Steps For Meeting New Package Insert Requirements	62
Joshua Sharlin, Ph.D., Resume.....	63
Appendix I, Full Prescribing Information, Examples and Regulations.....	70