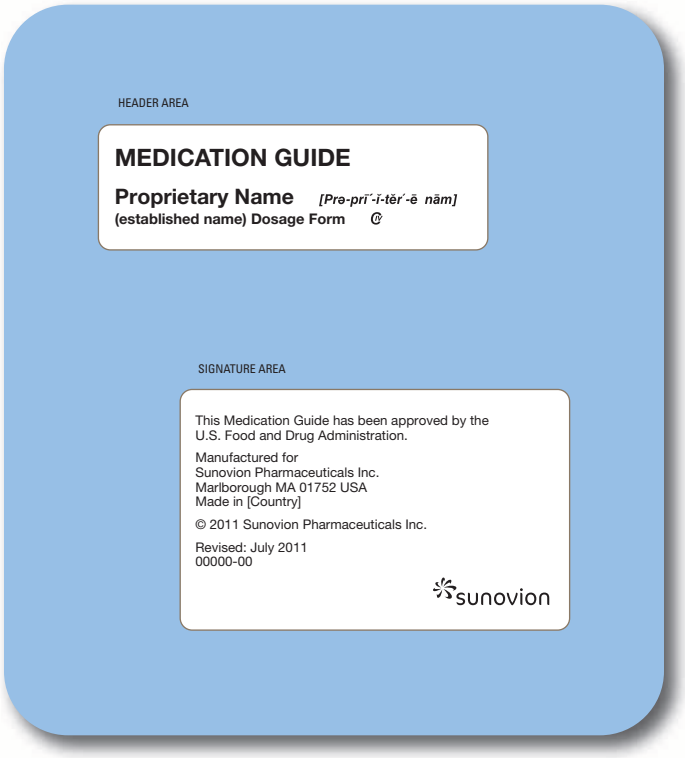


Medication Guide

Design and Content Guideline
Header and Signature Areas

Contents

Introduction

Welcome to the Medication Guide
Header and Signature Area Guideline.

The purpose of this Guideline is to provide a framework for the consistent development of Sunovion Medication Guide header and signature areas.

The Guideline is relational in nature. It shows the relative size and positioning of mandated content for a Sunovion Medication Guide's header and signature areas. A package designer may choose to maintain the relational spirit of the Guideline but adjust its implementation based on Medication Guide dimensions, to achieve legibility and an aesthetically pleasing presentation.

Please note that header and signature area content may change from Medication Guide to Medication Guide at the discretion of Sunovion Regulatory Affairs.

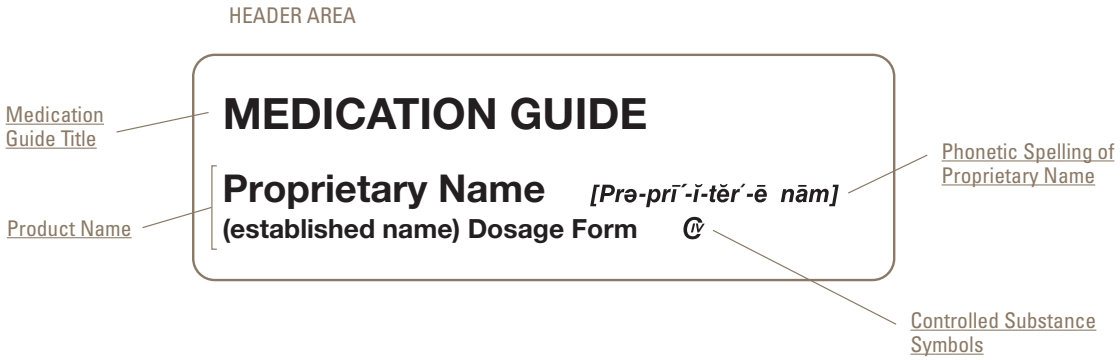
Additional Medication Guide body text information can be referenced by following this link to 21 CFR Section 208.20.

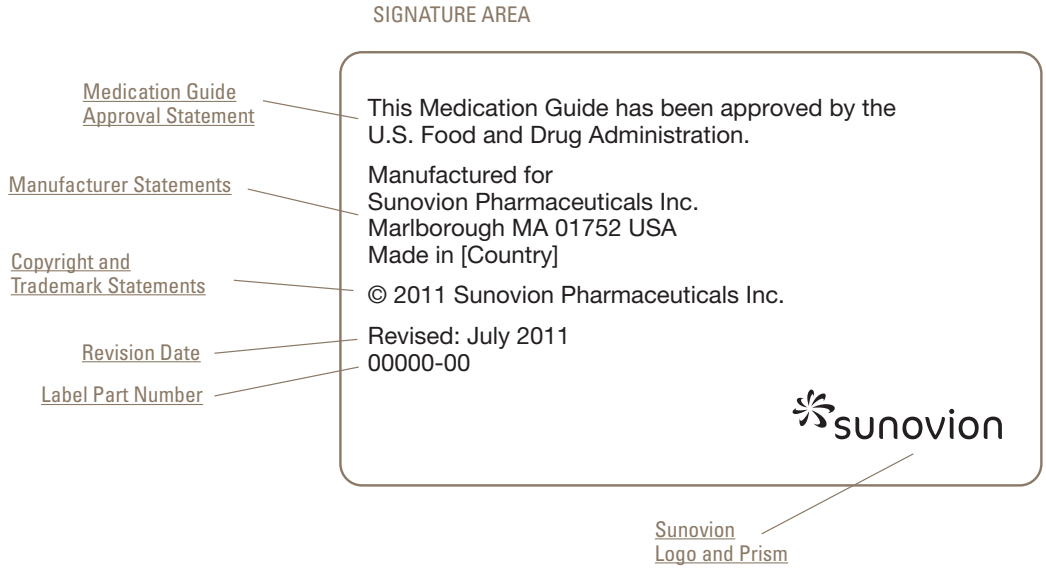
We hope you find this Guideline to be a useful tool and we welcome comments or questions to SunovionStyle@sunovion.com.

Consistent, compliant, and great packaging. That's our mission.

The Editors

Medication Guide Header and Signature Area Template





Controlled Substance Symbols

Approved Controlled Substance Symbols

Design Guidelines for Controlled Substance Symbols

Symbol size

Symbol should be 100–120% the height of the capital letters in Established Name or Dosage Form.

Symbol size must be large enough to easily identify the product's controlled substance designation.

Placement

Positioned right of, and on the same baseline as Established Name within the Header Area.

The horizontal space between Established Name and Symbol should be twice the width of Symbol.

Margins Designated by CMO.

Color Black.

Reference

21 CFR Section 1302.03. Symbol required; exceptions.

21 CFR Section 1302.04. Location and size of symbol on label and labeling.

Copyright and Trademark Statements

Approved Copyright and Trademark Statements

Copyright

© 2010, 2011 Sunovion Pharmaceuticals Inc. All rights reserved.

© 2011 Sunovion Pharmaceuticals Inc.

Trademark

When a product name, not licensed by Sunovion, appears with register mark ®:

[Product Name] is a registered trademark of [Company Name] and is used with permission.

When a product name, not licensed by Sunovion, appears with trademark ™*:*

[Product Name] is a trademark of [Company Name] and is used with permission.

Design Guidelines for Copyright and Trademark Statements

Font family Helvetica Neue Std.

Font weight Roman.

Font size

10–11 point suggested. 10 point minimum.

Relational size

Font size must be same as font size of Manufacturer Statements.

Placement

Signature Area, immediately following Manufacturer Statement.

Spacing between lines (leading): Baseline to baseline spacing between lines will be 110–120% of font size.

Spacing between paragraphs (paragraph leading): Baseline to baseline spacing between paragraphs will be 150–200% of font size.

Alignment: Left aligned.

Margins Designated by CMO.

Color Black.

Preferred Order of Signature Area Text

1) Medication Guide Approval Statement
2) Manufacturer Statements
3) Copyright and Trademark Statements
4) Revision Date
5) Label Part Number
6) Sunovion Logo and Prism

Paragraph treatment: Copyright and Trademark Statements, as well as each Signature Area Text category, should be a separate paragraph.

continues next page

Copyright and Trademark Statements

Reference

For trademark information, see 21 CFR Section 201.1 (h)(4): *Drugs; name and place of business of manufacturer, packer, or distributor.*

For copyright information, see 37 CFR Section 201.20: *Methods of affixation and positions of the copyright notice on various types of works*.

Guidance for determining or changing copyright date

Generally, copyright date is determined based on Sunovion's best estimate on piece "publication" date. This is the date the piece is distributed to the general public/consumer; typically this occurs when the piece arrives with the wholesaler or fulfillment center.

For existing packaging and labeling components:

Minor changes: No change or addition to copyright dates.

Medium changes (relevant but not significant changes): Add copyright date to those existing.

Major changes (new or significantly different label): Remove copyright date(s) and insert new date.

Label Part Number

Approved Label Part Number

00000-00

Design Guidelines for Label Part Number Format

Font family Helvetica Neue Std.

Font weight Roman.

Font size

10–11 point suggested. 10 point minimum.

Relational size

Font size must be same as font size of Manufacturer Statements.

Placement

Signature Area, immediately following Revision Date.

Spacing between lines (leading): Baseline to baseline spacing between lines will be 110–120% of font size.

Spacing between paragraphs (paragraph leading): Extra spacing between Revision Date and Label Part Number is not required.

Alignment: Left aligned.

Margins Designated by CMO.

Color Black.

Preferred Order of Signature Area Text

1) Medication Guide Approval Statement
2) Manufacturer Statement
3) Copyright and Trademark Statements
4) Revision Date
5) Label Part Number
6) Sunovion Logo and Prism

Paragraph treatment: Label Part Number, as well as each Signature Area Text category, should be a separate paragraph. Label Part Number does not require extra paragraph leading.

Manufacturer Statements

Approved Manufacturer Statements

Manufactured for Sunovion Pharmaceuticals Inc.
Marlborough MA 01752 USA

Manufactured for Sunovion Pharmaceuticals Inc.
Marlborough MA 01752 USA
Made in [Country]

Design Guidelines for Manufacturer Statements

Font family Helvetica Neue Std.

Font weight Roman.

Font size

10–11 point suggested. 10 point minimum.

Relational size

Font size must be same as font size of Medication Guide body copy.

Placement

Signature Area, immediately following Medication Guide Approval Statement.

Spacing between lines (leading): Baseline to baseline spacing between lines will be 110–120% of font size.

Spacing between paragraphs (paragraph leading): Baseline to baseline spacing between paragraphs will be 150–200% of font size.

Alignment: Left aligned.

Margins Designated by CMO.

Color Black.

Line break preference

Line break after "Inc." is preferred. Additional line break after "for" is acceptable.

Preferred Order of Signature Area Text

1) Medication Guide Approval Statement
2) Manufacturer Statement
3) Copyright and Trademark Statements
4) Revision Date
5) Label Part Number
6) Sunovion Logo and Prism

Paragraph treatment: Manufacturer Statements, as well as each Signature Area Text category, should be a separate paragraph.

References

21 CFR Section 208.20(8)(iii). Content and format of a Medication Guide.

21 CFR Section 201.1. Drugs; name and place of business of manufacturer, packer, or distributor.

Country of origin:
19 CFR Section 134.25. Containers or holders for repacked J-list articles and articles incapable of being marked.

19 CFR Section 134.26. Imported articles repacked or manipulated.

Medication Guide Approval Statement

Approved Medication Guide Approval Statement

This Medication Guide has been approved
by the U.S. Food and Drug Administration.

Design Guidelines for Medication Guide Approval Statement

Font family Helvetica Neue Std.

Font weight Roman.

Font size

10–11 point suggested. 10 point minimum.

Relational size

Font size must be same as font size of Manufacturer Statements.

Placement

Signature Area, immediately following Medication Guide text.

Spacing between lines (leading): Baseline to baseline spacing between lines will be 110–120% of font size.

Spacing between paragraphs (paragraph leading): Baseline to baseline spacing between paragraphs will be 150–200% of font size.

Alignment: Left aligned.

Margins Designated by CMO.

Color Black.

Preferred Order of Signature Area Text

1) Medication Guide Approval Statement
2) Manufacturer Statement
3) Copyright and Trademark Statements
4) Revision Date
5) Label Part Number
6) Sunovion Logo and Prism

Paragraph treatment: Medication Guide Approval Statement, as well as each Signature Area Text category, should be a separate paragraph.

Reference

21 CFR Section 208.20(a)(6). Content and format of a Medication Guide.

Medication Guide Title

Approved Medication Guide Title

MEDICATION GUIDE

Design Guidelines for Medication Guide Title

Font family Helvetica Neue Std.

Font weight Bold.

Font size

18 point suggested.

Placement

First line of text in the left column of the Medication Guide's first page.

Alignment: Left aligned.

Margins Designated by CMO.

Color Black.

Preferred Order of Header Area Text

1) Medication Guide Title
2) Product Name

Reference

21 CFR Section 208.20(a)(6). Content and format of a Medication Guide.

Phonetic Spelling of Proprietary Name

Approved Phonetic Spelling of Proprietary Name

[Prə-prī´-ĭ-tĕr´-ē nām]

Design Guidelines for Phonetic Spelling of Proprietary Name

Font family Helvetica Neue Std.

If phonetic characters unavailable:
Arial or ITC Stone Sans STD Phonetic.

Font weight Bold Italic.

Font size

11 point suggested.

Relational size

Font size must be same as font size of Established Name.

Placement

Positioned right of, and on the same baseline as Proprietary Name within the Header Area.

Margins Designated by CMO.

Color Black.

Reference

21 CFR Section 208.20(b)(1). Content and format of a Medication Guide.

Product Name

Approved Product Name Format

Proprietary Name
(established name) Dosage Form

Note: Proprietary Name, Established Name, and Dosage Form may not be replaced with brand logo.

Design Guidelines for Proprietary and Established Name

Font family Helvetica Neue Std.

Font weight Bold.

Font size

Proprietary Name: 16 point suggested.

Established Name: 11 point suggested. Height of capital letters in Established Name must be at least 55% the height of capital letters in Proprietary Name.

Placement

Header Area, immediately following the Medication Guide Title.

Spacing from baseline of Medication Guide Title to baseline of Proprietary Name should be at least 200% of the font size of Proprietary Name.

Spacing from baseline of Proprietary Name to baseline of Established Name and Dosage Form should be 130% of the font size of Established Name.

Alignment: Left aligned.

Margins Designated by CMO.

Color Black.

Reference

21 CFR Section 208.20(a)(7). Content and format of a Medication Guide.

21 CFR Section201.10(g)(2)–(h)(2). Drugs; statement of ingredients.

Revision Date

Approved Revision Date

Revised: [Month] [Year] (e.g., Revised: July 2011)

Design Guidelines for Revision Date

Font family Helvetica Neue Std.

Font weight Roman.

Font size

10–11 point suggested. 10 point minimum.

Relational size

Font size must be same as font size of Manufacturer Statements.

Placement

Signature Area, immediately following Copyright Statements.

Spacing between lines (leading): Baseline to baseline spacing between lines will be 110–120% of font size.

Spacing between paragraphs (paragraph leading): Baseline to baseline spacing between paragraphs will be 150–200% of font size.

Alignment: Left aligned.

Margins Designated by CMO.

Color Black.

Preferred Order of Signature Area Text

1) Medication Guide Approval Statement
2) Manufacturer Statement
3) Copyright and Trademark Statements
4) Revision Date
5) Label Part Number
6) Sunovion Logo and Prism

Paragraph treatment: Revision Date, as well as each Signature Area Text category, should be a separate paragraph.

Reference

21 CFR Section 208.20(b)(8)(iv). Content and format of a Medication Guide.

Sunovion Corporate Branding

Approved Sunovion Logo and Prism

Design Guidelines for Sunovion Corporate Branding

Graphic size

Width of the Sunovion Logo and Prism should be 30 mm.

Placement

Signature Area, immediately following Label Part Number.

Spacing from baseline of Label Part Number to baseline of Sunovion Logo and Prism should be 150–160% the height of the Sunovion Logo and Prism.

Alignment: Right aligned.

Sunovion Logo and Prism cannot be modified in any way.

Color Black.