

Patient Information

Design and Content Guideline Header and Signature Areas

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Introduction

Welcome to the Patient Information Header and Signature Area Guideline.

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

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

Please note that content may change from component to component at the discretion of Sunovion Regulatory Affairs.

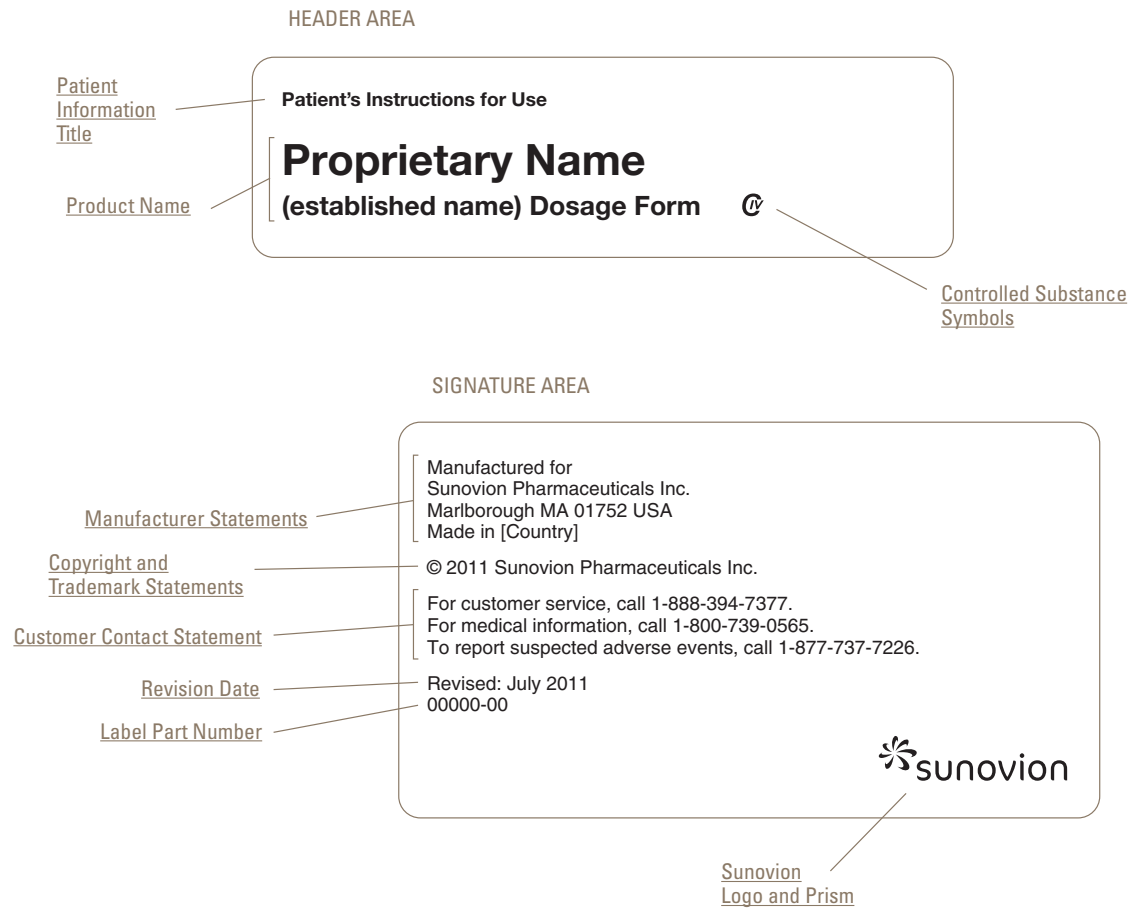
Additional Patient Information body text specifications can be referenced by following this link to [21 CFR Section 201.57](#).

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

Patient Information 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

8–10 point suggested. 8 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) Manufacturer Statements
- 2) Copyright and Trademark Statements
- 2) Customer Contact 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.

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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.

Customer Contact Statements

Approved Customer Contact Statements

For customer service, call 1-888-394-7377.
 For medical information, call 1-800-739-0565.
 To report suspected adverse events, call 1-877-737-7226.

Note: Other statements may be directed by Sunovion Regulatory Affairs and/or Consumer Affairs.

Design Guidelines for Customer Contact Statement

Font family Helvetica Neue Std.

Font weight Roman.

Font size

8–10 point suggested. 8 point minimum.

Relational size

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

Placement

Signature Area, immediately following Copyright and Trademark 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) Manufacturer Statements
- 2) Copyright and Trademark Statements
- 2) Customer Contact Statements
- 4) Revision Date
- 5) Label Part Number
- 6) Sunovion Logo and Prism

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

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

8–10 point suggested. 8 point minimum.

Relational size

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

Placement

Signature Area, immediately following Revision Date Statement.

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) Manufacturer Statements
- 2) Copyright and Trademark Statements
- 2) Customer Contact 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

8–10 point suggested. 8 point minimum.

Relational size

Font size must be same as font size of Patient Information body copy.

Placement

Signature Area, immediately following Patient Information body copy.

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) Manufacturer Statements
- 2) Copyright and Trademark Statements
- 2) Customer Contact 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 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.

Patient Information Title

Approved Patient Information Title

Patient Information
Patient Information for Use
Patient's Instructions for Use

Design Guidelines for Patient Information Title

Font family Helvetica Neue Std.

Font weight Bold.

Font size
8–12 point suggested. 8 point minimum.

Relational size
Font size should be 100–120% of font size of Patient Information body copy.

Placement
First line of text in the left column of the Patient Information's first page.

Alignment: Left aligned.

Margins Designated by CMO.

Color Black.

Preferred Order of Header Area Text

- 1) Patient Information Title
- 2) Product Name

Product Name

Approved Product Name Format

Proprietary Name (established name) Dosage Form

Note: Proprietary Name, Established Name, and Dosage Form may be replaced with black or grayscale brand logo, pre-approved by Regulatory Affairs to ensure compliance with labeling regulations.

Design Guidelines for Proprietary and Established Name

Font family Helvetica Neue Std.

Font weight Bold.

Font size

Proprietary Name font size should be a minimum 200% and a maximum of 250% of Patient Information body copy font size.

Height of capital letters in Established Name must be 55% the height of capital letters in Proprietary Name.

Placement

Header Area, immediately following the Patient Information Title.

Spacing from baseline of Patient Information 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 must be at least 120% the font size of Established Name. Address any descenders in Proprietary Name either by adding extra line spacing or careful kerning.

Alignment: Left aligned.

Margins Designated by CMO.

Color Black.

Preferred Order of Header Area Text

- 1) Patient Information Title
- 2) Product Name

Reference

21 CFR Section 201.10(g)(2)–(h)(2). Drugs; statement of ingredients.

21 CFR Section 201.57. Specific requirements on content and format of labeling for human prescription drug and biological products described in 201.56(b)(1).

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

8–10 point suggested. 8 point minimum.

Relational size

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

Placement

Signature Area, immediately following Customer Contact 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) Manufacturer Statements
- 2) Copyright and Trademark Statements
- 2) Customer Contact 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 201.57. Specific requirements on content and format of labeling for human prescription drug and biological products described in 201.56(b)(1).

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.