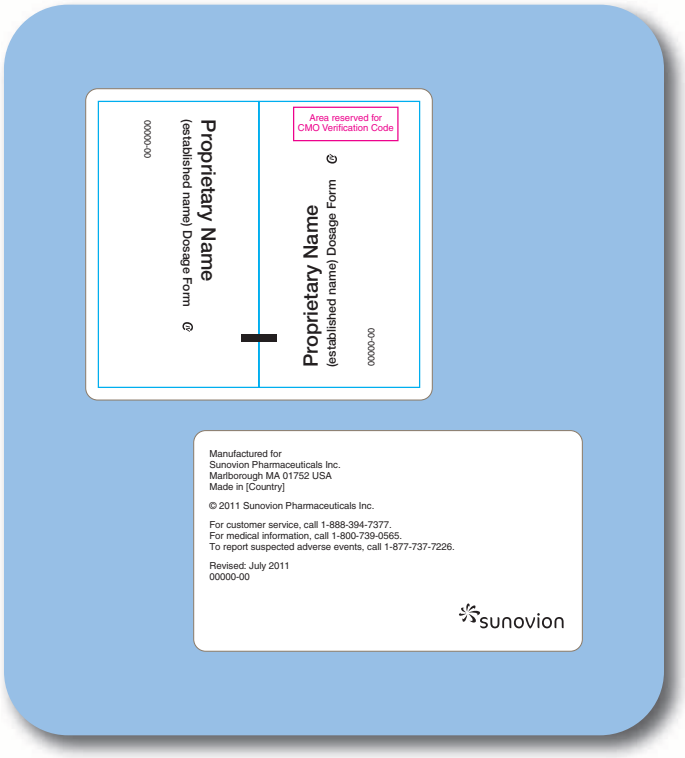


Prescribing Information

Design and Content Guideline
Header and Signature Areas

Contents

Introduction

Welcome to the Prescribing Information Header and Signature Area Guideline.

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

The Guideline is relational in nature. It shows the relative size and positioning of mandated content for Sunovion Prescribing Information header and signature areas. A package designer may choose to maintain the relational spirit of the Guideline but adjust its implementation based on Prescribing 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.

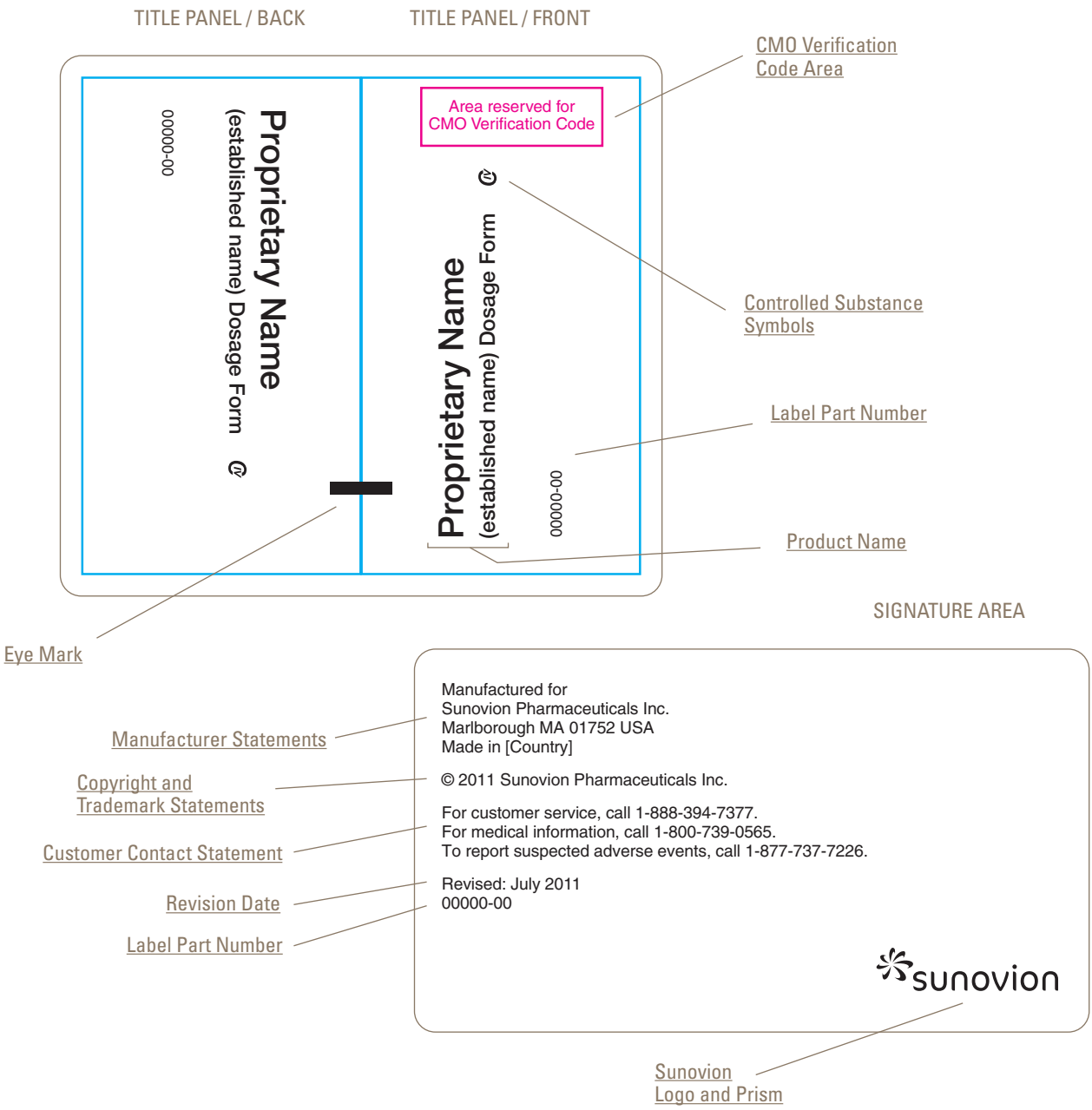
Additional Prescribing Information body text specifications can be referenced by following this link to 21 CFR Section 201.57.

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

Prescribing Information Header and Signature Area Template



CMO Verification Code Area

Approved handling of CMO Verification Code Area

Area Reserved for
CMO Verification Code

Design Guidelines for CMO Verification Code Area

Font family Helvetica Neue Std.

Font weight Medium.

Font size

6–8 point suggested. Panel size dependent.

Placement

Location designated by Contract Manufacturing Organization (CMO).

Quiet Zone

CMO will include required quiet zone for the bar code in area reserved for CMO verification.

Color

Keyline border: Magenta (does not print).

Text: Magenta (does not print).

Verification Code Handling

CMO creates and places the verification code in the boxed area.

Exception: CMO may require Sunovion to add a Verification Code, e.g., Pharmacode.

In this case, the CMO Verification Code Area would not be called out, but would be replaced with the actual code, built according to Engineering Drawing Specifications.

Exception: CMO may use text for verification, and may provide specs for text to be placed in the reserved area.

Pharmacode

Number of bars/value: Assigned by CMO.
Thick bar: 1.5 mm.
Thin bar: 0.5 mm.
Space between bars: 1 mm.
Bar height: Assigned by CMO.
Read direction: Assigned by CMO.
Color of bars: Black preferred.

Exception: CMO may direct a pharmacode or equivalent with different specifications.

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.

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.

If space constraints: Condensed.

Font size

6–7 point suggested. 6 point minimum.

Relational size

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

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.

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.

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.

If space constraints: Condensed.

Font size

6–7 point suggested. 6 point minimum.

Relational size

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

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.

Eye Mark

Approved Eye Mark

Graphic size

Rectangle, built according to Engineering Drawing Specifications.

Color

Black.

Placement

Location designated by Contract Manufacturing Organization (CMO).

Label Part Number

Approved Label Part Number

00000-00

Design Guidelines for Label Part Number Format

Font family Helvetica Neue Std.

Font weight Roman.

If space constraints: Condensed.

Font size

6–7 point suggested. 6 point minimum.

Relational size

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

Placement

Signature Area, immediately following Revision Date Statement. Front and/or Back Title Panel.

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 in Signature Area. In Title Area, spacing from baseline of Dosage Form to baseline of Label Part Number will be 300–400% 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: Label Part Number, as well as each Signature Area Text category, should be a separate paragraph. Signature Area Label Part Number does not require extra paragraph leading.

Preferred Order of Header Area Text

1) Product Name
2) Label Part Number

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.

If space constraints: Condensed.

Font size

6–7 point suggested. 6 point minimum.

Relational size

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

Placement

Signature Area, immediately following Prescribing 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 201.57. Specific requirements on content and format of labeling for human prescription drug and biological products described in 201.56(b)(1).

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.

Product Name

Approved Product Name Format

Proprietary Name
(established name) Dosage Form

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 Condensed.

Font size

Proprietary Name: 18–24 point suggested. Panel size dependent.

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

Placement

First line of text in the upper left corner of the Header Area.

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) Product Name
2) Label Part Number

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.

If space constraints: Condensed.

Font size

6–7 point suggested. 6 point minimum.

Relational size

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

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.