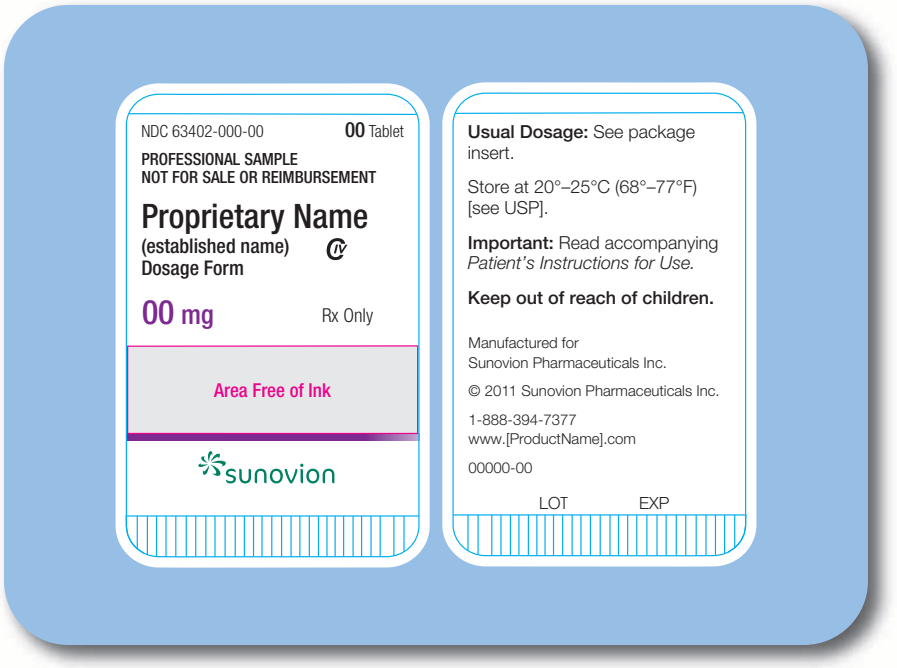



# Two-Sided Blister Lidding

## Complete Design and Content Guideline

**Contents**

## Introduction

*Welcome to the Two-Sided Blister Lidding Complete Design and Content Guideline.*

The purpose of this Guideline is to provide a framework for the consistent development of two-sided blister lidding for Sunovion, while at the same time allowing flexibility in design and product branding.

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

It is recommended that the placement of the Sunovion Logo and Prism and the NDC number be used as starting points for the design of two-sided blister lidding, and lay out from there.

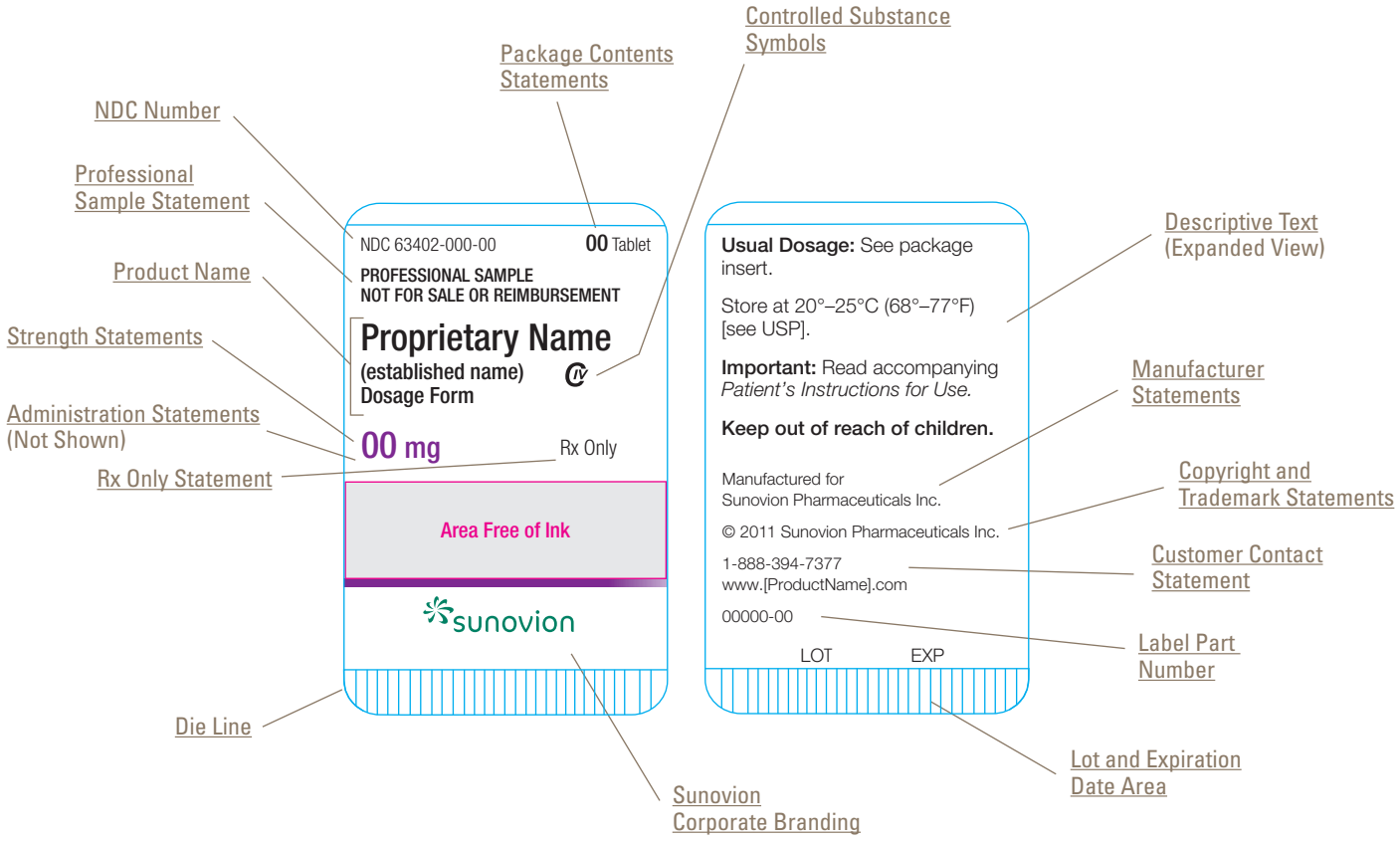
Please note that content may change from blister lidding to blister lidding at the discretion of Sunovion Regulatory Affairs.

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*

# Two-Sided Blister Lidding Template

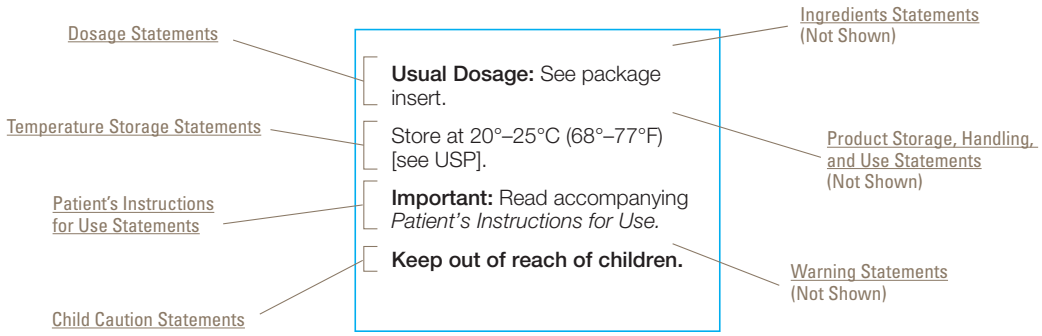



## Global Two-Sided Blister Lidding Considerations

*Ink:* All ink colors and coverage are subject to evaluation based on extractable/leachable data and impact on product quality.

*Text placement:* Reference physical samples and engineering drawings to verify that text will not be placed in seal areas.

# Two-Sided Blister Lidding Template–Descriptive Text Expanded View



# Administration Statements

## Approved Administration Statements

***For products with actuator***

FOR INTRANASAL USE WITH [PROPRIETARY NAME] NASAL ACTUATOR ONLY

FOR ORAL INHALATION WITH [PROPRIETARY NAME] ACTUATOR ONLY

***For inhalation or nasal spray products***

FOR ORAL INHALATION ONLY

FOR INTRANASAL USE ONLY

## Design Guidelines for Administration Statements

***Font family*** Helvetica Neue Std.

***Font weight*** Light Condensed.

***Font size***

7–9 point suggested. Panel size dependent.

***Relational size***

Font size should be 120% the size of the NDC number.

***Font tracking***

For statements that appear in all capital letters, increase tracking as follows: QuarkXPress setting at +6; Illustrator and InDesign settings at +30.

***Placement***

Principal display panel, beneath Strength Statement.

Spacing from baseline of Strength Statement to baseline of Administration Statement should be 250% of font size, or adjusted as necessary to achieve an equal amount of white space above and below the Strength Statement.

*Alignment:* Left aligned.

***Margins***

Margins from all edges of blister lidding must be a minimum of $^{3}/_{32}$" (2.5 mm; 7 points).

***Reference***

21 CFR Section 201.5. Drugs; adequate directions for use.

# 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*

Principal display panel. 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.

*If space constraints:* Space between Established Name and Symbol can be reduced to the width of Symbol.

### *Margins*

Margins from all edges of blister lidding must be a minimum of $^{3}/_{32}$" (2.5 mm; 7 points).

### *Color*

*Light background color:* Black.

*Dark background color:* Reverse to white.

### *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*

*Preferred:*

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

*If space constraints:*

© 2010, 2011 Sunovion Pharmaceuticals Inc.

*Or, placed near the Manufacturer Statement:*

© 2010, 2011

### *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*** Light.

*If space constraints:* Light Condensed.

### *Font size*

5–8 point suggested. Panel size dependent.

### *Relational size*

Font size must be same as font size of Manufacturer and Customer Contact Statements.

### *Placement*

*Preferred:* Back panel, as part of the Manufacturer/Copyright/Contact 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*

Margins from all edges of blister lidding must be a minimum of $^{3}/_{32}$" (2.5 mm; 7 points).

***Color*** *Light background color:* Black.

*Dark background color:* Reverse to white.
Font weight should change to Medium.

### *Preferred Order of Manufacturer/Copyright/Contact Text*

1) Manufacturer Statements
2) Copyright and Trademark Statements
3) Customer Contact Statement

*Paragraph treatment:* Copyright and Trademark Statement, as well as each Manufacturer/Copyright/Contact 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 Statement

## Approved Customer Contact Statement

1-888-394-7377
www.[ProductName].com

*Note: Other statements may be directed by Sunovion brand team.*

## Design Guidelines for Customer Contact Statement

***Font family*** Helvetica Neue Std.

***Font weight*** Light.

*If space constraints:* Light Condensed.

### *Font size*

5–8 point suggested. Panel size dependent.

### *Relational size*

Font size must be same as font size of Manufacturer and Copyright and Trademark Statements.

### *Placement*

*Preferred:* Back panel, as part of the Manufacturer/ Copyright/Contact 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*

Margins from all edges of blister lidding must be a minimum of $^{3}/_{32}$" (2.5 mm; 7 points).

### *Color*

*Light background color:* Black.

*Dark background color:* Reverse to white. Font weight should change to Medium.

### *Preferred Order of Manufacturer/ Copyright/Contact Text*

1) Manufacturer Statements
2) Copyright and Trademark Statements
3) Customer Contact Statement

*Paragraph treatment:* Customer Contact Statement, as well as each Manufacturer/Copyright/Contact Text category, should be a separate paragraph.

### *Reference*

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

# Ingredients Statements

## Approved Ingredients Statements*

Each [unit] contains: [established name] 000 mg.

Contains no preservatives.

## Design Guidelines for Ingredients Statements

***Font family*** Helvetica Neue Std.

***Font weight*** Light.

*If space constraints:* Light Condensed.

### *Font size*

6–8 point suggested. Panel size dependent.

### *Relational size*

All Descriptive Text must be the same size.

### *Placement*

*Preferred:* Back panel within Descriptive Text block (see Preferred Order of Descriptive Text).

*Spacing between lines (leading):* When statements are longer than one line, 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*

Margins from all edges of blister lidding must be a minimum of $^{3}/_{32}$" (2.5 mm; 7 points).

### *Color*

*Light background color:* Black.

*Dark background color:* Reverse to white. Font weight should change to Medium.

### *Preferred Order of Descriptive Text*

1) Ingredients Statements
2) Dosage Statements
3) Product Storage, Handling, and Use Statements
4) Temperature Storage Statements
5) Patient's Instructions for Use Statements
6) Warning Statements
7) Child Caution Statements

*Paragraph treatment:* Ingredients Statements, as well as each Descriptive Text category, should be a separate paragraph.

### *Reference*

21 CFR Section 201.10. Drugs; statement of ingredients.

*Other formulation ingredients may be needed.

# Dosage Statements

**Approved Dosage Statements** (depending on form of product, e.g., tablet, liquid; and dosage administration)

**Usual Dosage:** One tablet at bedtime.

**Usual Dosage:** One tablet per day with food.

**Usual Dosage:** See package insert.

Use only as directed by your physician. Do not exceed recommended dose.

## Design Guidelines for Dosage Statements

***Font family*** Helvetica Neue Std.

### *Font weight*

Medium and Light as shown in the Approved Statements above.

*If space constraints:* Medium and Light Condensed.

### *Font size*

6–8 point suggested. Panel size dependent.

### *Relational size*

All Descriptive Text must be the same size.

### *Placement*

*Preferred:* Back panel within Descriptive Text block (see Preferred Order of Descriptive Text).

*Spacing between lines (leading):* When statements are longer than one line, 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*

Margins from all edges of blister lidding must be a minimum of $^{3}/_{32}$" (2.5 mm; 7 points).

### *Color*

*Light background color:* Black.

*Dark background color:* Reverse to white.
Font weights should change to Bold and Medium.

### *Preferred Order of Descriptive Text*

1) Ingredients Statements
2) Dosage Statements
3) Product Storage, Handling, and Use Statements
4) Temperature Storage Statements
5) Patient's Instructions for Use Statements
6) Warning Statements
7) Child Caution Statements

*Paragraph treatment:* Dosage Statements, as well as each Descriptive Text category, should be a separate paragraph.

# Product Storage, Handling, and Use Statements

## Approved Product Storage, Handling, and Use Statements

**Shake well before use.**

**Shake gently before use.**

***For foil pouches***

Unit-dose vials should remain stored in the protective foil pouch at all times.

Once the foil pouch is opened, the vials should be used within two weeks.

Once removed from the foil pouch, the individual vials should be used within one week.

Open the foil pouch just prior to administration.

After opening the foil pouch, the unused vials should be returned to, and stored in, the pouch.

***For products with actuator***

For optimal results, canister should be at room temperature when used.

***For aerosol products***

**CONTENTS UNDER PRESSURE.** Do not puncture. Do not use or store near heat or open flame. Exposure to temperatures above 49°C (120°F) may cause bursting. Never throw canister into fire or incinerator.

***For concentrated products***

**Dilute before use.**

***For solutions***

**Discard if solution is not colorless.**

***For inhalation or nasal spray products***

**Avoid spraying in eyes.**

## Design Guidelines for Product Storage, Handling, and Use Statements

***Font family*** Helvetica Neue Std.

***Font weight***

Medium and Light as shown in the Approved Statements above.

*If space constraints:* Medium and Light Condensed.

***Font size***

6–8 point suggested. Panel size dependent.

***Relational size***

All Descriptive Text must be the same size.

***Placement***

*Preferred:* Back panel within Descriptive Text block (see Preferred Order of Descriptive Text).

*Spacing between lines (leading):* When statements are longer than one line, 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.

*continues next page*

# Product Storage, Handling, and Use Statements

### *Margins*

Margins from all edges of blister lidding must be a minimum of 3/32" (2.5 mm; 7 points).

### *Color*

*Light background color:* Black.

*Dark background color:* Reverse to white.
Font weights should change to Bold and Medium.

### *Preferred Order of Descriptive Text*

1) Ingredients Statements
2) Dosage Statements
3) Product Storage, Handling, and Use Statements
4) Temperature Storage Statements
5) Patient's Instructions for Use Statements
6) Warning Statements
7) Child Caution Statements

*Paragraph treatment:* Product Storage, Handling, and Use Statements, as well as each Descriptive Text category, should be a separate paragraph.

*If space constraints:* Product Storage, Handling, and Use Statements can be combined into one paragraph.

# Temperature Storage Statements

## Approved Temperature Storage Statements

**Storage:** Store at 20°–25°C (68°–77°F); excursions permitted to 15°–30°C (59°–86°F) [see USP Controlled Room Temperature].

Store at 20°–25°C (68°–77°F) [see USP Controlled Room Temperature].

Store at 25°C (77°F) [see USP Controlled Room Temperature].

Store at 25°C (77°F) [see USP].

Do not freeze.

Protect from freezing temperatures and direct sunlight.

Protect from light and excessive heat.

Keep tightly closed.

## Design Guidelines for Temperature Storage Statements

### *Font family*

Helvetica Neue Std.

### *Font weight*

Medium and Light as shown in the Approved Statements above.

*If space constraints:* Medium and Light Condensed.

### *Font size*

6–8 point suggested. Panel size dependent.

### *Relational size*

All Descriptive Text must be the same size.

### *Usage of en dash and degree symbol*

Temperature range uses an en dash (–) with no space around it. There is no space between the degree sign (°) and "C" or "F".

### *Placement*

*Preferred:* Back panel within Descriptive Text block (see Preferred Order of Descriptive Text).

*Spacing between lines (leading):* When statements are longer than one line, 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*

Margins from all edges of blister lidding must be a minimum of $^{3}/_{32}$" (2.5 mm; 7 points).

### *Color*

*Light background color:* Black.

*Dark background color:* Reverse to white.
Font weights should change to Bold and Medium.

### *Preferred Order of Descriptive Text*

1) Ingredients Statements
2) Dosage Statements
3) Product Storage, Handling, and Use Statements
4) Temperature Storage Statements
5) Patient's Instructions for Use Statements
6) Warning Statements
7) Child Caution Statements

*Paragraph treatment:* Temperature Storage Statements should be combined into one paragraph. Each Descriptive Text category should be a separate paragraph.

### *Reference*

US Pharmacopeia. USP-29-NF24. Statements/labeling of the immediate containers or package insert.

# Patient's Instructions for Use Statements

## Approved Patient's Instructions for Use Statements

**Attention Pharmacist** (or "**Physician**" for samples)**:** Dispense with accompanying *Patient's Instructions for Use.*

**Important:** Read accompanying *Patient's Instructions for Use.*

## Design Guidelines for Patient's Instructions for Use Statements

***Font family*** Helvetica Neue Std.

### *Font weight*

Medium and Light as shown in the Approved Statements above.

*If space constraints:* Medium and Light Condensed.

### *Font size*

6–8 point suggested. Panel size dependent.

### *Relational size*

All Descriptive Text must be the same size.

### *Placement*

*Preferred:* Back panel within Descriptive Text block (see Preferred Order of Descriptive Text).

*Spacing between lines (leading):* When statements are longer than one line, 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*

Margins from all edges of blister lidding must be a minimum of $^{3}/_{32}$" (2.5 mm; 7 points).

### *Color*

*Light background color:* Black.

*Dark background color:* Reverse to white.
Font weights should change to Bold and Medium.

### *Preferred Order of Descriptive Text*

1) Ingredients Statements
2) Dosage Statements
3) Product Storage, Handling, and Use Statements
4) Temperature Storage Statements
5) Patient's Instructions for Use Statements
6) Warning Statements
7) Child Caution Statements

*Paragraph treatment:* Patient's Instructions for Use Statements, as well as each Descriptive Text category, should be a separate paragraph.

# Warning Statements

## Approved Warning Statements

**In case of accidental ingestion, immediately contact your physician, pharmacist, or a poison control center.**

**Please see full prescribing information including BOXED WARNINGS.**

## Design Guidelines for Warning Statements

***Font family*** Helvetica Neue Std.

***Font weight*** Medium.

*If space constraints:* Medium Condensed.

### *Font size*

6–8 point suggested. Panel size dependent.

### *Relational size*

All Descriptive Text must be the same size.

### *Placement*

*Preferred:* Back panel within Descriptive Text block (see Preferred Order of Descriptive Text).

*Spacing between lines (leading):* When statements are longer than one line, 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*

Margins from all edges of blister lidding must be a minimum of $^{3}/_{32}$" (2.5 mm; 7 points).

### *Color*

*Light background color:* Black.

*Dark background color:* Reverse to white. Font weight should change to Bold.

### *Preferred Order of Descriptive Text*

1) Ingredients Statements
2) Dosage Statements
3) Product Storage, Handling, and Use Statements
4) Temperature Storage Statements
5) Patient's Instructions for Use Statements
6) Warning Statements
7) Child Caution Statements

*Paragraph treatment:* Warning Statements, as well as each Descriptive 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).

# Child Caution Statements

## Approved Child Caution Statements

***For all packaging***

Keep out of reach of children.

***For non-child resistant packaging, add***

Package not child resistant.

## Design Guidelines for Child Caution Statements

***Font family*** Helvetica Neue Std.

***Font weight*** Medium.

*If space constraints:* Medium Condensed.

### *Font size*

6–8 point suggested. Panel size dependent.

### *Relational size*

All Descriptive Text must be the same size.

### *Placement*

*Preferred:* Back panel within Descriptive Text block (see Preferred Order of Descriptive Text).

*Spacing between lines (leading):* When statements are longer than one line, 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*

Margins from all edges of blister lidding must be a minimum of $^{3}/_{32}$" (2.5 mm; 7 points).

### *Color*

*Light background color:* Black.

*Dark background color:* Reverse to white. Font weight should change to Bold.

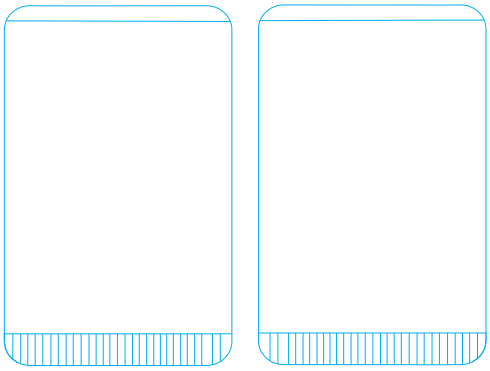
### *Preferred Order of Descriptive Text*

1) Ingredients Statements
2) Dosage Statements
3) Product Storage, Handling and Use Statements
4) Temperature Storage Statements
5) Patient's Instructions for Use Statement
6) Warning Statements
7) Child Caution Statements

*Paragraph treatment:* Child Caution Statements, as well as each Descriptive Text category, should be a separate paragraph.

# Die Line

## Approved Die Line



## Design Guidelines for Two-Sided Blister Lidding Die Line

### *Die Line Supplier*

CMO will provide die line at 100% of final component size. The die will show where the two-sided blister lidding will be cut.

CMO will indicate, either on the die or on a separate engineering drawing, the position of any areas needed for their packaging equipment, such as Lot and Expiration date imprinting or verification code areas, and any areas that need to be free of ink.

The die supplied by the CMO will become the foundation for the design.

Die can be edited according to Sunovion's preferences for line weight and color, but should not be edited for size or shape.

### *Line Weight*

Stroke weight of all rules should be 1/2 point and should be set to overprint.

### *Stroke Color*

*Color type:* Spot.

*Color name:* Die.

*Color definition:* 100% cyan preferred. Any alternate color except black can be used if cyan does not provide adequate contrast.

### *Helpful Information*

Die supplied by CMO may contain useful information not needed for Sunovion's design approval process, such as blister measurements or multiple placement options. This information should remain with the file, but may be moved to an invisible layer.

### *Exception*

CMO may request their die be used in full and unedited.

# Label Part Number

## Approved Label Part Number

00000-00

## Design Guidelines for Label Part Number Format

***Font family*** Helvetica Neue Std.

***Font weight*** Light.

*If space constraints:* Light Condensed.

### *Font size*

5–8 point.

### *Placement*

*Preferred:* Back panel, following Manufacturer/ Copyright/Context text.

*Alignment:* Left aligned.

*Spacing between copyright information and Label Part Number (paragraph leading):* Baseline to baseline spacing between paragraphs will be 150–200% of font size.

### *Margins*

Margins from all edges of blister lidding must be a minimum of 3/32" (2.5 mm; 7 points).

### *Color*

*Light background color:* Black.

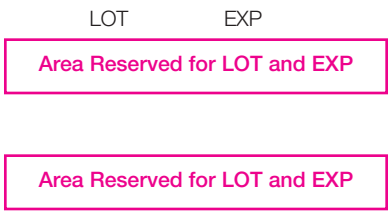
*Dark background color:* Reverse to white. Font weight should change to Medium.

### *Exception*

If Label Part Number is used for online verification (i.e., Vision System), refer to Engineering Drawing Specifications for all parameters.

# Lot and Expiration Date Area

## Approved Style for Lot and Expiration Date Area




## Design Guidelines for Lot and Expiration Date Area

***Font family*** Helvetica Neue Std.

### *Font weight*

*Lot and Exp text:* Light.

*Boxed text:* Medium.

### *Font size*

4–8 point suggested. Panel size dependent.

### *Placement*

Location designated by Contract Manufacturing Organization (CMO).

### *Margins*

Designated by CMO.

### *Color*

*Keyline border:* Magenta (does not print).

*Text:* Magenta (does not print).

*Box color:* Transparent, or color designated in engineering drawing.

### *References*

21 CFR Section 201.18. Drugs; significance of control numbers.

21 CFR Section 201.17. Drugs; location of expiration date.

# 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]

Mfd. for Sunovion Pharmaceuticals Inc.

Sunovion Pharmaceuticals Inc.

Sunovion

## Design Guidelines for Manufacturer Statements

***Font family*** Helvetica Neue Std.

***Font weight*** Light.

*If space constraints:* Light Condensed.

### *Font size*

5–8 point suggested. Panel size dependent.

### *Relational size*

Font size must be same as font size for Copyright and Trademark and Customer Contact Statements.

### *Placement*

*Preferred:* Back panel, as part of the Manufacturer/ Copyright/Contact Text, directly following Descriptive 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*

Margins from all edges of blister lidding must be a minimum of $^{3}/_{32}$" (2.5 mm; 7 points).

### *Color*

*Light background color:* Black.

*Dark background color:* Reverse statement to white. Font weight should change to Medium.

### *Line break preference*

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

### *Preferred Order of Manufacturer/ Copyright/Contact Text*

1) Manufacturer Statements
2) Copyright and Trademark Statements
3) Customer Contact Statement

*Paragraph treatment:* Manufacturer Statement, as well as each Manufacturer/Copyright/Contact 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.

# NDC Number

## Approved NDC Number

NDC 63402-000-00

## Design Guidelines for NDC Number

***Font family*** Helvetica Neue Std.

***Font weight*** Light Condensed.

### *Font size*

6–8 point suggested. Panel size dependent.

### *Relational size*

Font size must be same as font size for Professional Sample Statements.

### *Placement*

The first line of text in the upper left corner of the principal display panel.

*Alignment:* Left aligned.

### *Margins*

Margins from all edges of blister lidding must be a minimum of $^{3}/_{32}$" (2.5 mm; 7 points).

### *Color*

*Light background color:* Black.

*Dark background color:* Reverse to white. Font weight should change to Medium.

### *Reference*

21 CFR Section 207.35. Notification of registrant; drug establishment registration number and drug listing number.

21 CFR Section 201.2. Drugs and devices; National Drug Code numbers.

# Package Contents Statements

## Approved Package Contents Statements

Net Contents: 00 g

***For tablets***

**00** Tablets

## Design Guidelines for Package Contents Statements

***Font family*** Helvetica Neue Std.

### *Font weight*

Medium Condensed and Light Condensed as shown in the Approved Statements above.

### *Relational size*

Same font size as NDC Number. Numbers (shown in Medium Condensed in the above Package Contents Statements) should be 125% of the font size of NDC Number.

### *Placement*

First line of text in the upper right corner of the principal display panel.

*Alignment:* Right aligned. Base align with NDC Number.

### *Margins*

Margins from all edges of blister lidding must be a minimum of $^{3}/_{32}$" (2.5 mm; 7 points).

### *Color*

*Light background color:* Black.

*Dark background color:* Reverse to white. Font weight should change to Bold and Medium.

### *Reference*

21 CFR Section 201.51. Declaration of net quantity of contents.

# 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 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*** Medium Condensed.

### *Font size*

Proprietary Name capital letter height should be a minimum 150% the height of the capital letters in Sunovion Logo and Prism.

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

### *Relational size*

The design objective is for the Product Name to have visual prominence over the Sunovion Logo and Prism. The package designer should exercise judgment, adjusting the size of the Product Name or the Sunovion Logo and Prism for a panel where the Proprietary Name guideline of 150% does not achieve the desired result.

### *Placement*

Principal display panel.

Established Name and Dosage Form may appear on the same line or break into two lines as shown above, directly below Proprietary Name. When two lines, spacing from baseline of Established Name to baseline of Dosage Form must be 110% the font size.

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.

Spacing from baseline of Professional Sample Statement to baseline of Proprietary Name should be a minimum of 150% of the font size of Proprietary Name.

### *Margins*

Margins from all edges of blister lidding must be a minimum of $^{3}/_{32}$" (2.5 mm; 7 points).

### *Color*

*Light background color:* Black.

*Dark background color:* Reverse to white. Font weight should change to Bold.

### *Reference*

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

# Professional Sample Statements

## Approved Professional Sample Statements

PROFESSIONAL SAMPLE – NOT FOR SALE OR REIMBURSEMENT

PROFESSIONAL SAMPLE
NOT FOR SALE OR REIMBURSEMENT

## Design Guidelines for Professional Sample Statements

***Font family*** Helvetica Neue Std.

***Font weight*** Medium Condensed.

### *Font size*

6–8 point suggested. Panel size dependent.

### *Relational size*

Font size must be the same as font size of NDC Number.

### *Font tracking*

For statements that appear in all capital letters, increase tracking as follows: QuarkXPress setting at +6; Illustrator and InDesign settings at +30.

### *Placement*

The second line of text in the upper left corner of the principal display panel, directly below NDC Number.

*Spacing between lines (leading):* If Professional Sample Statement is two lines, baseline to baseline spacing between lines should be 105% of font size.

*Spacing between paragraphs (paragraph leading):* Baseline to baseline spacing between NDC and first line of Professional Sample Statement should be 150% of font size.

*Alignment:* Left aligned.

### *Margins*

Margins from all edges of blister lidding must be a minimum of $^{3}/_{32}$" (2.5 mm; 7 points).

### *Color*

*Light background color:* Black.

*Dark background color:* Reverse to white. Font weight should change to Bold.

### *Reference*

21 CFR Section 203.38. Sample lot or control numbers; labeling of sample units.

# Rx Only Statement

## Approved Rx Only Statement

Rx Only

## Design Guidelines for Rx Only Statement

***Font family*** Helvetica Neue Std.

***Font weight*** Light Condensed.

### *Font size*

7–9 point suggested. Panel size dependent.

### *Relational size*

Font size should be 120% the font size of NDC number.

### *Placement*

Principal display panel.

*If blister lidding includes an Administration Statement:*
Spacing from baseline of Administration Statement to baseline of Rx Only Statement should be 150–200% of font size.

*If Rx Only Statement follows an element other than the Administration Statement:*
Spacing from baseline of the prior element to baseline of Rx Only Statement should be 200% of font size.

*Alignment:* Left aligned.

*If space constraints:* Rx Only Statement can appear on the same baseline as the Strength Statement, right aligned.

### *Margins*

Margins from all edges of blister lidding must be a minimum of $^{3}/_{32}$" (2.5 mm; 7 points).

### *Color*

*Light background color:* Black.

*Dark background color:* Reverse to white. Font weight should change to Medium.

### *Reference*

Guidance for Industry. Implementation of Section 126 of the Food and Drug Administration Modernization Act of 1997 — Elimination of Certain Labeling Requirements.

# Strength Statements

## Approved Strength Statements

00 mg

## Design Guidelines for Strength Statements

***Font family*** Helvetica Neue Std.

***Font weight*** Medium Condensed.

### *Font size*

Number(s) in Strength Statement should be the same size as capital letters in the Proprietary Name. All other text should be 80% the size of the numbers.

### *Placement*

Principal display panel, beneath Product Name.

Spacing from baseline of Established Name to baseline of Strength Statement should be 125% of the font size of the number(s) in Strength Statement.

*Alignment:* Left aligned.

### *Margins*

Margins from all edges of blister lidding must be a minimum of $^{3}/_{32}$" (2.5 mm; 7 points).

### *Color*

Strength or product differentiation color as specified by Sunovion Regulatory Affairs and Brand Team.

### *Reference*

21 CFR Section 201.51. Declaration of net quantity of contents.

# Sunovion Corporate Branding

***Preferred:***

## Approved Sunovion Corporate Branding for Two-Sided Blister Lidding


### Design Guidelines for Sunovion Corporate Branding

***Graphic size***

Minimum width of the Sunovion Logo and Prism is 15 mm.

***Placement***

Principal display panel.

Minimum quiet zone around Sunovion Corporate Branding is 1/8".

*Sunovion Logo and Prism:* Sunovion Logo and Prism cannot be modified in any way.

***Color***

*Strength or Product Differentiation Color band (shown in purple above):* Strength differentiation color, or one of the product's color palette if there is only one presentation. Gradient from 100% to 30%.

*Sunovion Logo and Prism:* PMS 341.

## Approved Sunovion Logo and Prism


### Design Guidelines for Sunovion Logo and Prism

***Graphic size***

Minimum width of the Sunovion Logo and Prism is 15 mm.

***Placement***

Lower right corner of the principal display panel.

Minimum quiet zone around Sunovion Logo and Prism is 1/8" (3 mm; 9 points).

Sunovion Logo and Prism cannot be modified in any way.

***Color*** PMS 341 or black.