

Strength/Metered Dose Statements

Approved Strength/Metered Dose Statements

00 mg

00 mcg/actuation

00 Metered Inhalations

00 mcg/actuation

00 Metered Actuations

00 mcg/00 mL

Design Guidelines for Strength/Metered Dose 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.

Metered Dose Statements should be the same size as Established Name.

Exception: On spine, number(s) in Strength Statement should be 150% of the supply description [“00 day supply of Proprietary Name (established name) Dosage Form”]. All other text in the Strength Statement on the spine should be 80% of the number(s) in the statement.

Placement

Beneath Product Name on principal display panel and any panel where Product Name appears.

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.

Spacing from baseline of Strength Statement to baseline of Metered Dose Statement should be 125–150% of the font size of Metered Dose Statement.

Alignment: Left aligned.

Exception: On spine, right aligned, centered vertically.

Margins

Margins from all edges of blister wallet panels must range from 1/8" (3 mm; 9 points) to 1/4" (6 mm; 18 points).

Color

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

Metered Dose Statement: Black.

Reference

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