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.

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.

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.

Margins

Margins from all edges of label must be a minimum of 1/16" (1.5 mm; 4.5 points).

Color

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

Metered Dose Statement: Black.

Reference

<u>21 CFR Section 201.51</u>. Declaration of net quantity of contents.