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

5-8 point suggested. Panel size dependent.

Relational size

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

Placement

Principal display panel.

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

If label does not include an Administration Statement: Spacing from baseline of Strength/Metered Dose Statement to baseline of Rx Only Statement should be 200% of font size.

Alignment: Left aligned.

Margins

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

Color

Light background color: Black.

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

Reference

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