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

12–14 point suggested. Panel size dependent.

Relational size

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

Placement

Principal display panel.

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

If carton 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 carton panels must range from $^1/_8$" (3 mm; 9 points) to $^1/_4$" (6 mm; 18 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.