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

10–12 point suggested. Panel size dependent.

Relational size

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

Placement

Principal display panel.

If foil pouch 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.

Margins

Margins from the seal area to any foil pouch panel must be a minimum of 1/8" (3 mm; 9 points).

Color

Light background color or foil: Black.

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

Preferred background color: Foil pouch background prints white.

Reference

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