Administration Statements

Approved Administration Statements

For products with actuator

FOR INTRANASAL USE WITH [PROPRIETARY NAME] NASAL ACTUATOR ONLY

FOR ORAL INHALATION WITH [PROPRIETARY NAME] ACTUATOR ONLY

For inhalation or nasal spray products

FOR ORAL INHALATION ONLY FOR INTRANASAL USE ONLY

Design Guidelines for Administration Statements

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 size of the NDC number.

Font tracking

For statements that appear in all capital letters, increase tracking as follows: QuarkXPress setting at +6; Illustrator and InDesign settings at +30.

Placement

Principal display panel, beneath Strength/Metered Dose Statement.

Spacing from baseline of Strength/Metered Dose Statement to baseline of Administration Statement should be 250% of font size, or adjusted as necessary to achieve an equal amount of white space above and below the Strength/Metered Dose Statement.

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

<u>21 CFR Section 201.5</u>. Drugs; adequate directions for use.