

Product Name

Approved Product Name Format

Proprietary Name (established name) Dosage Form

Note: Proprietary Name, Established Name, and Dosage Form may be replaced with black or grayscale brand logo, pre-approved by Regulatory Affairs to ensure compliance with labeling regulations.

Design Guidelines for Proprietary and Established Name

Font family Helvetica Neue Std.

Font weight Bold.

Font size

Proprietary Name font size should be a minimum 200% and a maximum of 250% of Patient Information body copy font size.

Height of capital letters in Established Name must be 55% the height of capital letters in Proprietary Name.

Placement

Header Area, immediately following the Patient Information Title.

Spacing from baseline of Patient Information Title to baseline of Proprietary Name should be at least 200% of the font size of Proprietary Name.

Spacing from baseline of Proprietary Name to baseline of Established Name and Dosage Form must be at least 120% the font size of Established Name. Address any descenders in Proprietary Name either by adding extra line spacing or careful kerning.

Alignment: Left aligned.

Margins Designated by CMO.

Color Black.

Preferred Order of Header Area Text

- 1) Patient Information Title
- 2) Product Name

Reference

21 CFR Section 201.10(g)(2)–(h)(2). Drugs; statement of ingredients.

21 CFR Section 201.57. Specific requirements on content and format of labeling for human prescription drug and biological products described in 201.56(b)(1).