

Product Name

Approved Product Name Format

Proprietary Name (established name) Dosage Form

Note: Proprietary Name, Established Name, and Dosage Form may not be replaced with brand logo.

Design Guidelines for Proprietary and Established Name

Font family Helvetica Neue Std.

Font weight Bold.

Font size

Proprietary Name: 16 point suggested.

Established Name: 11 point suggested. Height of capital letters in Established Name must be at least 55% the height of capital letters in Proprietary Name.

Placement

Header Area, immediately following the Medication Guide Title.

Spacing from baseline of Medication Guide 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 should be 130% of the font size of Established Name.

Alignment: Left aligned.

Margins Designated by CMO.

Color Black.

Reference

21 CFR Section 208.20(a)(7). Content and format of a Medication Guide.

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