Medication Guide Approval Statement

Approved Medication Guide Approval Statement

This Medication Guide has been approved
by the U.S. Food and Drug Administration.

Design Guidelines for Medication Guide Approval Statement

Font family   Helvetica Neue Std.

Font weight   Roman.

Font size

10–11 point suggested. 10 point minimum.

Relational size

Font size must be same as font size of Manufacturer Statements.

Placement

Signature Area, immediately following Medication Guide text.

Spacing between lines (leading): Baseline to baseline spacing between lines will be 110–120% of font size.

Spacing between paragraphs (paragraph leading): Baseline to baseline spacing between paragraphs will be 150–200% of font size.

Alignment: Left aligned.

Margins   Designated by CMO.

Color   Black.

Preferred Order of Signature Area Text

1)   Medication Guide Approval Statement
2)   Manufacturer Statement
3)   Copyright and Trademark Statements
4)   Revision Date
5)   Label Part Number
6)   Sunovion Logo and Prism

Paragraph treatment: Medication Guide Approval Statement, as well as each Signature Area Text category, should be a separate paragraph.

Reference

21 CFR Section 208.20(a)(6). Content and format of a Medication Guide.