Revision Date

Approved Revision Date

Revised: [Month] [Year] (e.g., Revised: July 2011)

Design Guidelines for Revision Date

Font family Helvetica Neue Std.

Font weight Roman.

If space constraints: Condensed.

Font size

6–7 point suggested. 6 point minimum.

Relational size

Font size must be same as font size of Prescribing Information body copy.

Placement

Signature Area, immediately following Customer Contact Statements.

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) Manufacturer Statements
- 2) Copyright and Trademark Statements
- 2) Customer Contact Statements
- 4) Revision Date
- 5) Label Part Number
- 6) Sunovion Logo and Prism

Paragraph treatment: Revision Date, as well as each Signature Area Text category, should be a separate paragraph.

Reference

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