

Manufacturer Statements

Approved Manufacturer Statements

Manufactured for Sunovion Pharmaceuticals Inc.
Marlborough MA 01752 USA

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Marlborough MA 01752 USA
Made in [Country]

Design Guidelines for Manufacturer Statements

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 Medication Guide body copy.

Placement

Signature Area, immediately following Medication Guide Approval Statement.

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.

Line break preference

Line break after “Inc.” is preferred. Additional line break after “for” is acceptable.

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: Manufacturer Statements, as well as each Signature Area Text category, should be a separate paragraph.

References

21 CFR Section 208.20(8)(iii). Content and format of a Medication Guide.

21 CFR Section 201.1. Drugs; name and place of business of manufacturer, packer, or distributor.

Country of origin:

19 CFR Section 134.25. Containers or holders for repacked J-list articles and articles incapable of being marked.

19 CFR Section 134.26. Imported articles repacked or manipulated.