

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.

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 Prescribing Information body copy.

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

References

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).

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.