Manufacturer Statements

Approved Manufacturer Statements

Manufactured for Sunovion Pharmaceuticals Inc. Marlborough MA 01752 USA

Manufactured for Sunovion Pharmaceuticals Inc. Marlborough MA 01752 USA Made in [Country] Mfd. for Sunovion Pharmaceuticals Inc.

Sunovion Pharmaceuticals Inc.

Sunovion

Note: It is preferred to remove "ugh" from "Marlborough" on small labels over removing "Mfd. for".

Design Guidelines for Manufacturer Statements

Font family Helvetica Neue Std.

Font weight Light.

If space constraints: Light Condensed.

Font size

4–7 point suggested. Panel size dependent. Sunovion approval required for size below 4 point.

Relational size

Font size must be same as font size for Copyright and Trademark and Customer Contact Statements.

Placement

Side panel, as part of the Manufacturer/Copyright/ Contact Text, directly following Descriptive 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

Margins from all edges of label must be a minimum of 1/16" (1.5 mm; 4.5 points).

Colo

Light background color: Black.

Dark background color: Reverse statement to white. Font weight should change to Medium.

Line break preference

Line break after "Inc." is preferred. Additional line break after "for" is acceptable.

Preferred Order of Manufacturer/ Copyright/Contact Text

- 1) Manufacturer Statements
- 2) Copyright and Trademark Statements
- 3) Customer Contact Statement

Paragraph treatment: Manufacturer Statement, as well as each Manufacturer/Copyright/Contact Text category, should be a separate paragraph.

References

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

Country of origin:

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

<u>19 CFR Section 134.26</u>. Imported articles repacked or manipulated.