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General Requirements & Importance for Labeling of Medical Devices: A Review

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Abstract: Medical device manufacturers see labeling as a important element for maintaining compliance and high safety and character standards, enhancing operational potency, ensuring brand consistency, and supporting company growth. The FDA does not review promotional materials for medical device labeling. Marketing and advertising material for medical devices are not surveyed and cleared by the FDA, However, the regulatory body does make sure that the label and instructions of the product are accurate. They assure that the information on the labels allow for secure use and does not include unsupported claims. The label should be light and easily traceable. Labeling is different for a commercial device versus an investigational device.

Keywords: FDA, Medical device, label.

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