General Device Labeling Requirements

General Labeling Provisions

The general labeling requirements for medical devices are contained in 21 CFR Part 801. These regulations specify the minimum requirements for all devices. Later sections in this chapter discuss any additional requirements needed for specific categories of devices.

Name and Place of Business (21 CFR 801.1)

- The label of a device shall contain the name and place of business of manufacturer, packer, or distributor including the street address, city, state, and zip code.
- If the firm's street address is in the local telephone directory, the street address can be omitted.
- If the firm listed on the label is not the manufacturer, the firm information must be qualified by an appropriate statement such as, "Manufactured for..." or "Distributed by...."

Intended Use (21 CFR 801.4)

- If a packer, distributor, or seller intends a device for uses other than those intended by the person from whom he received the device, these parties must furnish adequate labeling in accordance with the new intended use.
- If a manufacturer knows or has information indicating that this device is to be used for conditions or purposes other than which it was intended, he is required to provide adequate labeling in accordance with such other uses. (An example of this might be a manufacturer of dental X-ray equipment who is routinely selling his product to podiatrists.)

Adequate Directions (21 CFR 801.5)

- "Adequate directions for use" means directions under which the layman can use a device safely and for the purposes intended. This includes:
  - Statements of all purposes for which and conditions under which the device can be used;
  - Quantity of dose for each use and usual quantities for persons of different ages and physical conditions;
  - Frequency of administration;
  - Duration of application;
  - Time of administration in relation to other factors;
  - Route or method of application; and
  - Any preparation necessary for use.

Information on exemptions from adequate directions for use (MedicalDevices/DeviceRegulationandGuidance/Overview/DeviceLabeling/GeneralDeviceLabelingRequirements/ucm051943.htm) requirement.

False or Misleading Statements (21 CFR 801.6)

- A device is misbranded if it makes a false or misleading statement with respect to another device, drug, food, or cosmetic.

Prominence of Statements (21 CFR 801.15)

- A word, statement or other required information may lack the required prominence and conspicuousness for the following reasons:
  - If it fails to appear on the part or panel that is displayed under customary conditions of purchase;
  - If the package contains sufficient space and the required information fails to appear on two or more panels, each of which is designed to render it to be displayed under customary conditions of purchase;
  - Failure to extend required labeling over package space provided;
  - Lack of sufficient label space for required labeling due to placement of non-required labeling of the package; or
  - Smallness or style of type, insufficient contrast between labeling and package background, designs which obscure labeling, or overcrowding of
Exemptions

- Exemptions may be granted in those instances where device labeling lacks sufficient space for required labeling provided that:
  - Existing label space is not taken up by including non-required information or by giving prominence to a portion of the required labeling; and
  - Existing label space is not used for any representations in a foreign language.
  - All labeling shall be in English with the exception of products distributed solely within Puerto Rico or a U.S. territory where the predominant language is other than English. In these instances the predominant language may be substituted for English.
  - If any representation on the device label or labeling appears in a foreign language, then all required labeling shall also appear in that foreign language.