



FDA Labeling Requirements

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When you review the General Device labeling requirements of the FDA such as for Radiation Emitting Devices and products under Federal standards 21 CFR part 1000, you will find that the concepts of "label" and labeling remain the same. For example, the "label" on a device might consist of a warning label on the console of an X-Ray system as well as a red indicator light on the panel. The "label" of a television receiver might consist not only of the name of the manufacturer, date of manufacture and user caution statements, but also of labels inside the receiver to high voltages and X-ray shielding.

Some of the items covered in this area are:

- 21 CFR 1020.10 Television Receivers
- 21 CFR 1020.20 Cold-Cathode Gas Discharge Tubes
- 21 CFR 1020.30 Diagnostic X-Ray Systems
- 21 CFR 1020.31 Radiographic Equipment
- 21 CFR 1030.10 Microwave and Radio Frequency Emitting Products
- 21 CFR 1040.1 Lasers
- 21 CFR 1050.10 Ultrasonic Therapy Products

Under FDA Good Manufacturing Practice (GMP), the Quality System (QS) regulation has several sections that have an impact on labeling. Section 21 CFR 820.80 requires inspection and testing of incoming materials including labeling. Section 21 CFR 820.120 deals with specific requirements for the control of labeling. Section 21 CFR 820.120 also applies to the application of labeling to ensure legibility under normal conditions of use during the expected life of the device. The FDA considers a device to be adulterated if these requirements are not met.

These regulatory issues bring the concept of labeling into a key design criteria rather than an after thought when finishing up a product design. There are a myriad of product specific requirements for labeling under the auspices of the FDA. Beyond the product specific requirements, there are broader guidelines from GMP and QS that deal with labeling. The serialization and dating of products is critical to potential future regulations that require retroactive actions. It is highly critical that the traceability be maintained.

You will find the use of anodized aluminum nameplates very common in laboratory devices. The aluminum is very resistant to cleaning and sterilizing solutions and the debossing of information onto the label can allow for long-term legibility. It is especially good to review all of the chemicals that come in contact with the instruments in a laboratory environment as some chemicals react poorly with some modern sheet plastics used for labeling.

As you begin to set your design criteria for a new product, a quick examination of regulations will allow for the definition of labeling methods for specific requirements. There are a number of alternatives to meet special requirements (e.g. autoclaving and highly corrosive chemicals), such as corrosion resistant overlays, insert-mold decoration and special adhesives. Lustre-Cal can provide manufacturers' information on special products for any regulatory issues.