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medical devices

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

CDRH

Labeling

Regulatory Requirements for Medical Devices

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Food and Drug Administration

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(Continued on inside back cover)

HHS Publication FDA 89-4203

Labeling

Regulatory Requirements for Medical Devices

Prepared by the
Division of Small Manufacturers Assistance
Office of Training and Assistance

Project Officer
Thomas Cardamone



August 1989

(This publication supersedes FDA 86-4203)

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
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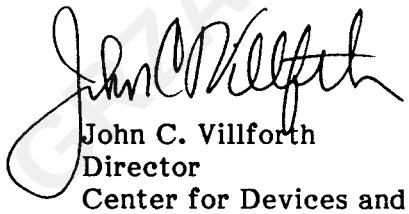
FOREWORD

In October 1982, the Food and Drug Administration established the Center for Devices and Radiological Health (CDRH) by merging the Bureau of Medical Devices and the Bureau of Radiological Health.

The Center develops and implements national programs to protect the public health in the fields of medical devices and radiological health. These programs are intended to assure the safety, effectiveness and proper labeling of medical devices, to control unnecessary human exposure to potentially hazardous ionizing and nonionizing radiation, and to ensure the safe, efficacious use of such radiation.

The Center publishes the results of its work in scientific journals and in its own technical reports. These reports provide a mechanism for disseminating results of CDRH and contractor projects. They are sold by the Government Printing Office and/or the National Technical Information Service.

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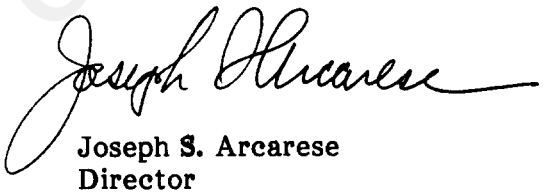


John C. Villforth
Director
Center for Devices and
Radiological Health

PREFACE

This publication explains label and labeling regulations and requirements for medical devices. The Food and Drug Administration has many labeling-related requirements to help assure that devices are used safely and effectively, including, but not limited to, provisions on misbranding in Section 502 of the Food, Drug, and Cosmetic (FD&C) Act. This publication explains such topics as advertising matter as labeling, what is false and misleading labeling, how prominent labeling information must be, what information must appear on containers as well as outside labels, adequate directions for use, prescription device requirements, and special labeling for particular devices or types of devices and uses.

The Medical Device Amendments to the FD&C Act mandated the establishment of "...an identifiable office to provide technical and other non-financial assistance to small manufacturers of medical devices to assist them in complying with the requirements of the Food, Drug, and Cosmetic Act." The Division of Small Manufacturers Assistance (DSMA) was established to meet these requirements. In addition to providing individual guidance and workshops, DSMA distributes a wide variety of printed materials such as regulations, policy statements, question-and-answer booklets, and other FDA documents that help manufacturers understand the substance and impact of FDA requirements, as well as the simplest or most effective ways to meet them. This publication contains explanations and examples of ways that companies can readily comply with labeling requirements. We hope the information contained in this publication will alert manufacturers to FDA labeling requirements, and prompt them to ask any questions they may have. Feel free to visit, write, or call DSMA toll free at 800-638-2041. The local phone number is (301) 443-6597.



Joseph S. Arcarese
Director
Office of Training and Assistance

ABSTRACT

Division of Small Manufacturers Assistance, Office of Training and Assistance, Center for Devices and Radiological Health. Labeling: Regulatory Requirements for Medical Devices. HHS Publication FDA 89-4203 (August 1989) (pp. 43).

This publication is Chapter 6 of the "Regulatory Requirements for Medical Devices - A Workshop Manual." It covers labeling requirements that device manufacturers, reconditioners, repackers, and relabelers must consider when a product requires labeling. Such labeling may include adequate instructions for use, servicing instructions, adequate warnings against uses that may be dangerous to health, or information that may be necessary for the protection of users.

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INTRODUCTION

The United States Food and Drug Administration develops and administers regulations under authority granted by laws passed by Congress that apply to food, drugs, cosmetics, biologics, radiation-emitting electronic products, and medical devices. Of the fourteen laws currently administered by FDA, three directly address the labeling of medical devices:

- **The Food, Drug, and Cosmetic (FD&C) Act** - The FD&C Act applies to food, drugs, cosmetics, biologics, and medical devices. Section 201 defines the terms "label" and "labeling" as they apply to medical devices and draws a distinction between these terms. Section 502(f)(1) and (2) requires that device labeling bear adequate directions for use, operating and servicing instructions, and either adequate warnings against dangerous uses to health, or information necessary for the protection of users.

- **The Fair Packaging and Labeling Act (FPLA)** - Because medical devices had previously been defined and regulated by the FD&C Act, Section 5 of the subsequently implemented FPLA Act refers to and makes use of the terms "label" and "labeling." Requirements of the FPLA apply to over-the-counter medical devices distributed by retail outlets.

- **The Radiation Control for Health and Safety Act (RCHSA)** - Section 358(h) of the RCHSA requires manufacturers or distributors of radiation-emitting electronic products, including medical devices, to place certification labeling on their devices.

The specific requirements of the above laws are implemented by the Secretary of the Department of Health and Human Services (DHHS) in the form of regulations. Initially, FDA which is a part of DHHS, drafts proposed regulations. These proposed regulations are then submitted by the Commissioner of the FDA to the Office of Management and Budget. After the required time frames for public comment have elapsed, these regulations are redrafted or resubmitted, and may eventually result in finalized labeling regulations. Final regulations are published in the FEDERAL REGISTER (FR) and have the force of law.

Labeling regulations promulgated under the above Acts which pertain to medical devices are currently found in the following Parts of Title 21 of the Code of Federal Regulations (CFR).

- General Device Labeling - 21 CFR PART 801
- In Vitro Diagnostic Products - 21 CFR PART 809
- Investigational Device Exemptions - 21 CFR PART 812
- Good Manufacturing Practices - 21 CFR PART 820
- General Electronic Products - 21 CFR PART 1010

Each of these parts or categories will be covered in detail in following sections of this chapter; however, before continuing, a few brief concepts and definitions from each Act applicable to labeling are discussed.

The FD&C Act is the primary law under which the FDA takes action against regulated products. Specifically:

- Sections 201(k) through 201(m) of the FD&C Act address labeling "definitions."

- Sections within Chapter III of the FD&C Act address prohibited acts with respect to food, drugs, cosmetics, and medical devices. These prohibitions deal with two major areas: "**adulteration**" and "**misbranding.**"

- Sections within Chapter V of the FD&C Act set forth specific instances whereby drugs or devices will be considered to be adulterated or misbranded by the FDA. The Radiation Control for Health and Safety Act applies both to medical and other radiation-emitting electronic devices. Labeling regulations based on this law pertain to FDA certification of electronic products and are found under 21 CFR Part 1010.

The medical aspects of the FPLA apply only to medical devices intended for sale to consumers from retail outlets. This Act refers to many sections of the FD&C Act. Labeling regulations based on the FPLA are found under 21 CFR Part 801.

The RCHSA applies both to medical and other radiation-emitting electronic devices. Labeling regulations based on this law pertain to FDA certification of electronic products and are found under 21 CFR Part 1010.

LABELS AND LABELING

Section 201 of the FD&C Act distinguishes between label and labeling. Certain provisions in Chapter V of the FD&C Act apply specifically to the "label" of the device, others are related to its "labeling." These terms are related, but not interchangeable. Of the two, the term "label" is more restricted. Generally, it consists of that part of the display confined to the device itself. On the other hand, "labeling" deals with the label on the device, and descriptive and informational literature that accompanies the device.

Section 201(k) defines "label" as a:

- "display of written, printed, or graphic matter upon the immediate container of any article..."

The term "immediate container" does not include package liners. Any word, statement, or other information appearing on the immediate container must also appear "on the outside container or wrapper, if any there be, of the retail package of such article, or is easily legible through the outside container or wrapper."

Section 201(m) defines "labeling" as:

- "all labels and other written, printed, or graphic matter

  (1) upon any article or any of its containers or wrappers, or
  (2) accompanying such article" at any time while a device is held for sale after shipment or delivery for shipment in interstate commerce.

The term "accompanying" is interpreted liberally to mean more than **physical** association with the product. It extends to posters, tags, pamphlets, circulars, booklets, brochures, instruction books, direction sheets, fillers, etc. "Accompanying" also includes labeling that is brought together with the device after shipment or delivery for shipment in interstate commerce.

Labeling and Advertising

The distinction between labeling and advertising, both of which draw attention to the article to be sold, is often superficial or nebulous. Both are used for a similar purpose, i.e., to provide information about the product. Thus, according to an appellate court decision: "Most, if not all advertising, is labeling. The term 'labeling' is defined in the FD&C Act as including all printed matter accompanying any article. Congress did not, and we cannot, exclude from the definition printed matter which constitutes advertising."

MISBRANDING

Section 502 of the FD&C Act contains provisions on misbranding and false or misleading labeling. Specific requirements and exemptions are contained in regulations promulgated under this Act as will be discussed in forthcoming sections in this chapter. A device is misbranded if:

- o Its labeling is false or misleading in any particular;
- o It is in package form and its label fails to contain the name and place of business of the manufacturer, packer, or distributor; and an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count;
- o Any required wording is not prominently displayed as compared with other wording on the device, or is not clearly stated;
- o Its label does not bear adequate directions for use including warnings against use in certain pathological conditions; or by children where its use may be dangerous to health; or against unsafe dosage, or methods, or duration of administration or application;
- o It is dangerous to health when used in the dosage or manner or with the frequency or duration prescribed, recommended or suggested in the labeling; or
- o It does not comply with the color additives provisions listed under Section 706 of the Act.

Sections 502 and 706 of the FD&C Act predate the medical device amendments and apply equally to food, drug, cosmetic, veterinary drugs, and biologics. The Medical Device Amendments of 1976 provided new authority for dealing specifically with the misbranding of medical devices. These additional provisions listed below state under what further circumstances a device is misbranded.

- o If the device's established name (if it has one), its name in an official compendium, or any common or usual name is not prominently printed in type at least half as large as that used for any proprietary name;
- o If the device is subject to a performance standard and it does not bear the labeling prescribed in that standard;
- o If there is a failure or refusal to comply with any requirement prescribed under the FD&C Act, Section 518 on notification and other remedies, or failure to furnish any materials or information requested by or under Section 519 on reports and records; or

- o If it has any representation that creates an impression of official approval because of the possession by the firm of an FDA registration or premarket notification number.

FALSE OR MISLEADING LABELING

Section 502(a) declares that a drug or device is misbranded if its labeling proves false or misleading in any particular. The phrase "false or misleading" is not confined in meaning to untrue, forged, fraudulent, or deceptive. In fact, the word, statement, or illustration may be true in the strict sense of the word; however, the labeling can be deemed by the FDA to be in violation of the law if it proves deceptive to the customer. It is not a necessary condition that the labeling should be flatly and baldly false; the word "misleading" in the Act means that labeling is deceptive if it is such as to create or lead to a false impression in the mind of the reader. A "false impression" may result not only from a false or deceptive statement, but may also be instilled in the mind of the purchaser by ambiguity or misdirection. It may also be caused by failure to inform the consumer of facts that are relevant to those statements actually made. In other words, the label that remains silent as to certain consequences may be as deceptive as the label that contains extravagant claims.

A device can be misbranded by making reference to a medical device registration, or a 510(k) premarket notification number assigned by FDA in response to a firm's filing requirements under the FD&C Act. Section 807.39 of 21 CFR, **Misbranding by reference to establishment registration or registration number**, and 807.97 of 21 cfr, **misbranding by reference to premarket notification**, state that the assigned numbers do not constitute official FDA approval of the device. Additionally, any representation that connotes FDA approval as a result of complying with the device regulations is misleading and constitutes misbranding.

Similiarly, a device can be misbranded by reference to an Investigational Device Exemption (IDE) or Premarket Approval (PMA). Section 301(l) prohibits the use on labeling of any device, or in any advertising relating to such device, of any representation or suggestion or approval of an application with respect to such device is in effect under Section 515, **IDE** or Section 520(g), **PMA**.

Examples of false representations are:

- o incorrect, inadequate or incomplete identification;
- o unsubstantiated claims of therapeutic value;
- o inaccuracies concerning condition, state, treatment, size, shape or style;
- o substitution of parts or material; and
- o use of the prefix "U.S." or other similar indication suggesting Government or Agency approval or endorsement of the product.

Examples of misleading labeling include:

- o ambiguity, half-truths, and trade puffery;
- o expressions of opinion or subjective statements; and

- o failure to reveal material facts, consequences that may result from use, or the existence of difference of opinion.

Examples of other objectionable labeling practices include:

- o deceptive pictorial matter;
- o misleading testimonials;
- o misleading list of parts or components; and
- o use of brand or trade names instead of "established names."

GENERAL DEVICE LABELING

INTRODUCTION

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.

GENERAL LABELING PROVISIONS

Name and Place of Business (801.1)

- o 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.
- o If the firm's street address is in the local telephone directory, the street address can be omitted.
- o 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 (801.4)

- o 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.
- o If a manufacturer knows or has information indicating that his 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 (801.5)

- o "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.

False or Misleading Statements (801.6)

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

Prominence of Statements (801.15)

- o 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 on the package; or
  - Smallness or style of type, insufficient contrast between labeling and package background, designs which obscure labeling, or overcrowding of labeling which renders it unreadable.
- o 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.
- o 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.

LABELING REQUIREMENTS FOR OVER-THE-COUNTER (NON-PRESCRIPTION) DEVICES

Principal Display Panel (801.60)

- o The principal display panel is that portion of the label which is intended to be displayed, presented, shown, or examined under customary conditions for retail sales. The area of the principal display panel is considered to be:
  - In the case of a rectangular package, the height x width of one side;
  - In the case of a cylindrical or nearly cylindrical package, 40% of height x circumference; or
  - In the case of any other shapes, 40% of the total surface area of the container, unless a more prominent site exists.

Statement of Identity (801.61)

- o The statement of identity of the device must be listed on the principal display panel.
  - It must list the common name of the device followed by a statement of its principal intended action(s);
  - Indications for use must be listed in the directions for use; and
  - The statement must be in bold type, reasonably related in size to the most prominent printed matter on the display panel, and must be in lines generally parallel to the base of the package on which it rests.

Net Quantity of Contents Statement (801.62)

- o The label of an over-the-counter (OTC) device in package form must contain a statement of net quantity of contents in terms of weight, measure, numerical count; or a combination of numerical count and weight, measure, or size, which are described below:
  - Count - If the declaration by count does not give accurate information as to the quantity, it shall be augmented by statements of weight, measure, or size;
  - Measure - In cases of established customer usage and trade custom where units of linear measure or measure of area are used, they shall be augmented when necessary with statements of weight measure or size. Liquid measure is to be expressed in terms of the U.S. gallon of 231 cu. in. and quart, pint, and fluid ounce subdivisions, and shall express the volume at 68 degrees Farenheit; and
  - Weight - Terms of weight are to be expressed in avoirdupois pound and ounce. Units of metric weight or measure are considered supplemental. The declaration may contain common or decimal fractions. Common fractions shall be reduced to their lowest terms.

- Placement - The declaration shall appear as a separate item on each principal display panel; and be separated by at least a space equal to the height of the lettering used in the declaration, from other information appearing above and below, and separated by at least twice the width of the letter "N" from labeling to the left or right.

o The height, ratio, and placement of lettering required on the principal display panel are a function of a number of variables related to package size, shape, composition, and the method of affixing the required labeling. This is described in detail under 21 CFR 801.62 (g) to (k).

EXEMPTIONS FROM ADEQUATE DIRECTIONS FOR USE

Prescription Device (801.109)

O A device which, because of any potentiality for harmful effect, or the supervision of the method of its use, or the collateral measures necessary to its use is not safe unless under a practitioner licensed by law to direct use of this device, and hence for which "adequate directions for use" cannot be written, is exempt from such provided:

- It is in the possession of either a licensed practitioner or persons lawfully engaged in the manufacture or distribution of the product;

- Its labeling bears an Rx statement, i.e., "Caution: Federal law restricts this device to sale by or on the order of a (insert name of physician, dentist, or other licensed practitioner) ;"

- Its labeling bears information for use including, indications, effects, routes, methods, and frequency and duration of administration, and any relevant hazards, contraindications, side effects, and precautions under which the device can safely be used; and

- All labeling other than labels and cartons bears the date of issuance or date of the latest revision.

Retail Exemption (801.110)

o A device which is delivered to the ultimate user by a licensed practitioner in the course of his practice or upon prescription are required only to bear the name and address of the practitioner, directions for use, and any required cautionary statements.

Commonly Known Directions (801.116)

o A device is exempt from adequate directions for use if adequate directions for common uses are known to the ordinary individual.

In Vitro Diagnostics (801.119)

o Are exempt from adequate directions for use provided that they meet those requirements found in 809.10 (covered in the "In Vitro Diagnostic Product Labeling" section of this chapter).

Medical Devices Used in Manufacturing (801.122)

- o Devices used for processing, repacking, or manufacturing of another drug or device are exempt from adequate directions for use if they bear the statement: "Caution: For manufacturing, processing, or repacking."

Medical Devices Used in Teaching, Research, or Law Enforcement (801.125)

- o Devices for use in teaching, law enforcement, research, and analysis are exempt if the device is shipped or sold to, or in the possession of, persons lawfully engaged in instruction in pharmacy, chemistry, or medicine (not involving clinical use), law enforcement, or chemical analysis or physical testing.

Expiration of Exemptions (801.127)

- o Exemptions from adequate directions for use are terminated:
  - If devices are shipped to individuals other than those who are listed as exempt, or
  - If the devices are used for other than the exempted purposes.

OTHER EXEMPTIONS

Exemptions from Packaging and Labeling Requirements (801.150)

- o In-process devices that are being transported (in transit) from one manufacturing site to another are exempt if:
  - The person who introduced the product into commerce is the owner of the firm where the device is to be further processed.
  - The person introducing the product into commerce is not the owner, and the delivery is to be made under a written agreement which includes the names and addresses of the firms and listing those specifications necessary for further processing.
  - The shipments are unsterile devices, are labeled as sterile, are in transit to a contract sterilizer [801.150(e)], and are exempt only if both of the following are met:
    1) There is in effect a written agreement between the two parties containing:
       - i. names and addresses of both parties which is signed by both the person authorizing the shipment and the person in charge of the sterilization facility;
       - ii. instructions for maintaining records to assure total accountability;
       - iii. acknowledgment that the devices are nonsterile and being shipped for further processing;
       - iv. a statement detailing the sterilization process, sterilant media, equipment, and quality assurance controls to be used; and

2) Each pallet, carton, or other designated unit is conspicuously marked to indicate its nonsterile nature.

This exemption is void if the product is adulterated or misbranded, or if a copy of the agreement is not available for FDA inspection.

LABELING REQUIREMENTS FOR SPECIFIC DEVICES

Warning and Caution Statements (801.403)

- o This part contains recommended or suggested wording for warning and caution statements for the following devices:

  - Denture reliners, pads and cushions
  - Denture repair kits
  - Infrared generators (including heating pads)
  - Insulin syringes
  - Mechanical massagers and vibrators
  - Steam or turkish bath
  - Ultraviolet generators

Use Related Statements (801.405 to 801.430 as listed below)

- o Certain devices require specific labeling which may include not only package labeling, but informational literature, patient release forms, performance testing, and/or specific tolerances or prohibitions on certain ingredients. The following devices have additional labeling requirements:

  - Denture repair or refitting kits (801.405)
    Special labeling and directions are listed in this section.

  - Pessaries for intracervical and intrauterine use (801.408)
    This section specifies that stem types and wing-tip types are considered dangerous and thus automatically misbranded. Hollow tube types are permitted, but require a Rx legend.

  - Impact resistant lenses in sunglasses and eyeglasses (801.410)
    This section specifies that case hardening of glass lenses, statistical testing of plastic lenses, "drop ball" testing, and documentation of these activities are required.

  - Ozone emission levels (801.415)
    This section specifies that ozone emission is restricted to levels below 0.05 parts per million in certain devices, and not permitted at all for use in any medical conditions for which there is no proof of safety or efficacy.

  - Chlorofluorocarbon propellants (801.417)
    This section specifies the use is prohibited except for use in contraceptive foams and certain metered drug dosage forms as detailed under 21 CFR 2.125. Special labeling is required on devices using this propellant as listed under 801.425.

- Hearing aids (801.420)
  Labeling requirements related to warnings, directions to dispensers and users, and technical data are contained in this section. Conditions for sale requirements related to availability of instructional brochures, patient waivers, and recordkeeping requirements are contained in 801.421.

- Intrauterine contraceptives (801.427)
  Professional and patient labeling requirements related to description, indications, precautions, and warnings are contained in this section.

- Menstrual tampons (801.430)
  This section contains those labeling requirements related to Toxic Shock Syndrome (TSS) information, warnings, and advisories.

IN VITRO DIAGNOSTIC PRODUCT LABELING

INTRODUCTION

In vitro diagnostic products (IVD's) are those **reagents, instruments, and systems** intended for use in diagnosis of disease or other conditions, including a determination of the state of health, in order to cure, mitigate, treat, or prevent disease or its sequelae. Such products are intended for use in the collection, preparation, and examination of specimens taken from the human body. In vitro diagnostic (IVD) labeling requirements are located in 21 CFR Part 809. Numbers appearing in parentheses next to subject headings are the corresponding sections of 21 CFR. This section contains the basic requirements for label and labeling (package insert) as specified in the labeling regulations for in vitro diagnostic products.

Specific information on the development and drafting of labels and labeling is contained in the "Development of Device Labeling" section in this chapter.

LABEL REQUIREMENTS FOR THE IMMEDIATE CONTAINER [809.10(A)]

The label for IVD's must state the following information, except in cases where it is not applicable. In addition, all information must appear on the outside container or wrapper, or be easily legible through the outside container or wrapper.

If the presence of any label information will interfere with the test, the information may appear on the outside wrapper or container instead of the label.

If the immediate containers are too small, or otherwise unable to bear labels with sufficient space, then the required labeling as listed below annotated with an asterisk (*) may appear on the outer container **labeling** only.

Label requirements are as follows:

- o The established and proprietary names of the product, e.g., cholestrolometers;

* o The intended use or uses, e.g., pregnancy detection, diabetes screening, etc.;

* o A statement of warnings or precautions for users listed in 16 CFR part 1500 (hazardous substances) and any other warnings appropriate to user hazards, and a statement "For In Vitro Diagnostic Use;"

o Name and place of business of the manufacturer, packer, or distributor;

o Lot or control number traceable to the production history

- Multiple unit products must have traceability of the individual units;
- Instrument lot numbers must allow for traceability of subassemblies; and
- A multiple unit product that requires use of its components as a system should have the same lot number, or other suitable uniform identification, on all units.

* o For **Reagents:**

- Established (common or usual) name;
- Quantity, proportion, or concentration of all active ingredients; e.g., mg., weight per unit volume, mg./dl etc., and for reagents derived from biological materials the source and measure of its activity, e.g., bovine, I.U., etc.;
- Storage instructions, i.e., temperature, humidity, etc.;
- Instructions for manipulation of products requiring mixing or reconstitution;
- Means to assure that the product meets appropriate standards of purity, quality, etc., at the time of use, including one or more of the following:

i. expiration date (date beyond which the product is not to be used);

* ii. statement of any visual indication of alteration;

* iii. instructions for a simple check to assure product usefulness;

* - The net quantity of contents.

LABELING REQUIREMENTS FOR INSERTS AND OUTER PACKAGING [809.10(B)]

Labeling must contain in one place the following information in the FORMAT and ORDER listed below, except where information is not applicable, or as specified in a standard for a particular product class.

If the device is a reagent intended as a replacement in a diagnostic system, labeling may be limited to that information necessary to adequately identify the reagent and to describe its use in the system.

If the device is a multiple purpose instrument used for diagnostic purposes, and not committed to specific diagnostic procedures or systems, labeling can be restricted to those points annotated by an asterisk (*).

* o The proprietary and established product name;

* o The intended use of the product and whether it is a qualitative or quantitative type of procedure, e.g., screening, physician's office, home use, etc.;

- o Summary and explanation of the test, including a short history containing methodology and the special merits and limitations of the test;

- o The chemical, physical, physiological, or biological principles of the procedure.

- o For **Reagents**:

  - The common name, if any, and quantity, proportion, or concentration or each reactive ingredient; and for biological material, the source and measure of its activity;

  - Appropriate cautions or warnings listed in 16 CFR Part 1500; the statement: "For In Vitro Diagnostic Use;" and any other limiting statements appropriate to the intended use of the product;

  - Adequate directions for reconstitution, mixing, dilution, etc.;

  - Appropriate storage instructions;

  - A statement of purification or treatment required for use; and

  - Physical, biological, or chemical indications of instability or deterioration.

* o For **Instruments**:

  - Use or function;
  - Installation procedures and requirements;
  - Principles of operation;
  - Performance characteristics and specifications;
  - Operating instructions;
  - Calibration procedures, including equipment and/or materials;
  - Operational precautions and limitations;
  - Hazards; and
  - Service and maintenance information.

- o Specimen collection and preparation for analysis, describing:

  - Special precautions/preparations;
  - Additives necessary to maintain specimen integrity;
  - Known interfering substances; and
  - Recommended specimen storage, handling, and shipping instructions.

- o A step by step outline of recommended procedures from the reception of the specimen to the obtaining of results. In addition to the following, this should include a list of any points that might improve precision or accuracy:

  - A list of materials provided and instruction for use, e.g., reagents, equipment, etc.;

  - A list of necessary materials that are not provided (include details such as sizes, numbers, types, and quality);

  - A description of the amounts of reagents necessary, and parameters such as time, temperature, etc.;

- A statement related to final reaction stability and any time restrictions on accurate measurements;

- Details of calibration, identifying and listing any necessary preparation of the reference materials, samples, and blanks. Describe the calibration range including the highest and lowest values measured; and

- Details of necessary quality control procedures and materials, e.g., positive and negative controls, acceptable performance limits.

o Explanation of the procedure for calculating the unknown, including the definition of each component of the formula, a sample calculation, and the number of significant figures appropriate for the answer;

o Limitations of the procedure, e.g., identify situations which will have an adverse impact on test results;

o Expected values including the range and how it was established;

o Specific performance characteristics as appropriate including accuracy, specificity, precision, and sensitivity;

* o Bibliography;

* o Name and place of business of the manufacturer, packer, or distributor; and

* o Date of issuance of the last labeling revision by the firm.

EXEMPTIONS FROM LABELING REQUIREMENTS

Shipments or other deliveries of IVD devices are exempt from label and labeling requirements in the above headings and from standards listed under Part 861 provided the following conditions are met:

o A shipment or delivery for an investigation subject to Part 812, Investigational Device Exemption (IDE), if the device is in compliance with the subject IDE; **or**

o A shipment or delivery for an investigation that is **not** in compliance with Part 812 (most IVD's are exempt from the IDE because of the following labeling) if the following conditions are met:

- A product in the laboratory research phase, not represented as an IVD, that is prominently labeled: "For Research Use Only. Not for use in diagnostic procedures;" and

- A product that is being shipped or delivered for product testing prior to full commercial marketing that is prominently labeled: "For Investigationai Use Only. The performance characteristics of this product have not been established."

LABELING OF GENERAL PURPOSE LABORATORY REAGENTS AND EQUIPMENT

General purpose items include routine laboratory reagents such as hydrochloric acid and equipment such as glassware whose uses are generally known by persons trained in their use. They do not need to bear the directions for use listed under **Label Requirements for the Immediate Container** and **Labeling Requirements for Inserts and Outer Packaging**, if their labeling meets the requirements listed below. If the product packaging is too small to accommodate a label with sufficient space for the labeling, and if the product is packaged in an outer container which has all of the following on its **labeling,** then only those portions annotated with an asterisk (*) must be on the product **label**.

o **Reagents**:

* - The proprietary and established name;

- A declaration of the established name, if any, and quantity, proportion, or concentration of the reagent ingredient stated in a system generally recognized by the user;

- A statement of the purity and quality including a qualitative statement of any impurities. This can be satisfied by using a statement of conformity with a generally recognized and available standard;

- A statement of warnings or precautions for users as contained in the regulations in 16 CFR Part 1500 and any other appropriate warnings, and the statement: "For Laboratory Use;"

- Net quantity of contents in terms of weight or volume, or numerical count, or any combination thereof;

- Appropriate storage instructions;

* - Name and place of business of the manufacturer, packer, or distributor; and

* - A lot or control number traceable to the manufacturing history of the product.

o **Equipment**

- Product labeling need include only a statement adequately describing the product, its composition, and physical characteristics if necessary for its proper use.

LABELING FOR INVESTIGATIONAL AND 510(K) DEVICES

INTRODUCTION

An "investigational device" is a device that is the object of a clinical investigation or research involving one or more human subjects to determine its safety and effectiveness. This definition also includes "transitional devices" which are devices that had been previously regulated by the FDA as drugs prior to the passage of the Medical Device Amendments, for example, pregnancy test kits.

All newly registered medical device establishments and existing medical device firms introducing new or significantly modified devices must notify FDA of their intent to market the device at least 90 days before introducing the devices into commercial distribution. This is done via a 510(k) Premarket Notification submission which is required by that corresponding section of the FD&C Act. The purpose of this submission, which includes copies of proposed device labeling, is so that FDA can determine whether or not the device as labeled is substantially equivalent to one that was in commercial distribution prior to May 28, 1976. This includes Class I, II, and III devices, or a device that was placed onto the market after that date that was classified by FDA as Class I or Class II. The 510(k) process does not require manufacturers to demonstrate that their devices are identical to marketed devices; only that the devices and their labeled uses be substantially equivalent in terms of safety and effectiveness. Clinical data may be required before FDA can determine whether a device is substantially equivalent under a 510(k).

If a device is found by the FDA to be not substantially equivalent and placed into Class III, the firm must demonstrate proof of safety and efficacy to FDA prior to marketing. This demonstration is done via a Premarket Approval application (PMA). The PMA must contain data which show the device to be safe and effective. An approved Investigational Device Exemption (IDE) enables a device to be shipped to researchers in order to collect data before the device is cleared by FDA for commercial distribution.

FDA must approve IDE applications for significant risk devices. Non significant risk devices are subject only to Institutional Review Board (IRB) approval. The IDE exempts device sponsors and investigators from certain regulatory requirements, i.e., those related to: performance standards, misbranding, premarket approval, registration, and listing, for the duration of the study. The IDE application will contain an investigational protocol which details the nature of the study, and the nature of the data to be obtained and furnished to FDA as proof of safety and efficacy. The sponsor provides detailed information on device labeling in the investigational plan. This information may vary depending on the device and the nature of the study, and can extend to such items as any advertisements placed in order to recruit human subjects for the investigation.

PREMARKET NOTIFICATION [510(K)] LABELING

There is no application form, but there is a format for the 510(k) submission contained in 21 CFR 807.81 to 807.97. Information required in the submission includes: a description of the device and its specifications, the class into which the device has been placed by FDA, the firm's registration number, a statement comparing the device to others of comparable type, and copies of labeling and promotional literature. The proposed device labeling submitted in the 510(k) plays an important role.

Labeling information to be included in a 510(k) submission may include:

- o device labels;
- o packaging labeling;
- o special handling or storage conditions;
- o instructions and/or instruction manuals;
- o service manuals;
- o promotional literature such as advertisements, publications, etc.; and
- o other labeling requirements such as UL, F.C.C., etc.

If the device labeling makes new, previously unsubstantiated claims or promotes use of the device for purposes or conditions other than currently marketed similar devices, the FDA would most likely place the device into Class III and it would need premarket approval prior to marketing. In those instances where a device is substantially equivalent to an existing device, or technology currently in use, a firm should attempt to obtain 510(k) clearance rather than go for premarket approval. The savings in time and cost could be considerable.

IDE DEVICE LABELING REQUIREMENTS (21 CFR PART 812.5)

If a device is found by the FDA to be not substantially equivalent and placed into Class III, the firm must submit a PMA to FDA prior to marketing to demonstrate proof of safety and efficacy. The firm must first apply for an Investigational Device Exemption (IDE) to exempt them from certain regulatory requirements for the duration of the study. The IDE application will contain an investigational protocol which details the nature of the study, and the nature of the data to be obtained and furnished to FDA as proof of safety and efficacy. The firm provides detailed information on device labeling in the investigational protocol. This information may vary depending on the device and the nature of the study, and can extend to such items as any advertisements placed in order to recruit human subjects for the investigation. For example, product labeling should be sufficient to insure stability of the test article for the duration of the study (storage requirements, recalibration procedures), bear sufficient directions for proper administration, alert the user of the investigational status of the article, and detail procedures to follow in the event of patient injury.

In addition to any labeling requirements specified in the IDE study protocol, the following general labeling is required:

- Information required in 801.1, i.e., name and place of business of the firm, quantity, and in 801.109, the following statement: "CAUTION: Investigational Device. Limited by Federal (or United States) law to investigational use."
- A description of all relevant contraindications, hazards, adverse effects, interfering substances or devices, warnings and precautions.
- Absence of any statements that are false or misleading, or that represent the device as safe and effective for its investigational purpose.
- Any device shipped solely for use on laboratory animals must be labeled: "CAUTION - Device for investigational use in laboratory animals or other tests that do not involve human subjects."

GOOD MANUFACTURING PRACTICE LABELING REQUIREMENTS

INTRODUCTION

Medical device manufacturers must incorporate in their quality assurance (QA) program several elements that relate to labeling in order to meet the requirements of the GMP regulation. The QA program must be adequate to assure that labeling meets the GMP device master record requirements with respect to legibility, adhesion, etc., and assure that labeling operations are controlled so that correct labeling is always issued and used.

Because many activities must be performed and controlled during the development and use of labeling, Table 5.1 is presented as a checklist. It contains a typical sequence of events required to develop and control labeling.

Labeling includes equipment labels, control labels, package labels, directions for use, maintenance manuals, etc. The displays on CRT's and other electronic message panels are considered labeling if instructions, prompts, cautions, and parameter identification information are given.

Various sections of the GMP regulation have an impact on labeling: Section 820.20(a)(2) requires approval or rejection of packaging materials and labeling; and Section 820.40 requires buildings to be of suitable design and have sufficient space for packaging and labeling operations. Section 820.120 deals with specific requirements for the design and control of labeling. It applies to the design application of labeling to assure legibility under normal conditions of use over the expected life of the device; and also to inspection, handling, storage, and distribution of labeling. FDA considers a device to be adulterated if these requirements are not met. These requirements do not apply to the adequacy of labeling content, except to make sure the content meets the labeling specifications contained in the device master record. However, failure to comply with GMP requirements such as proofreading and change control could result in labeling content errors. In such cases, the device is misbranded and adulterated. Labeling content is covered in the section on "Development of Labeling."

Specifications are required in the device master record (820.181, 182) for the content and physical design parameters of labels. Labeling specifications are: engineering drawing and/or artwork for each label, appropriate inspection or control procedures, and appropriate procedures for attaching the labels. All procedures, drawings, and artwork must have the name of the preparer, an approval signature, and a date. The approval signature, date, etc., may be on the backside of artwork or on a label approval form. Further, artwork may contain only an identification code or title if the "content" of the artwork is duplicated on approved engineering drawings or adequately identified (cross-referenced) with respect to the label approval form.

Hardcopy labels, package inserts, and similar labeling are specified and purchased as components. For correct purchase and use of labeling, specifications are usually stated on engineering drawings and/or purchase specifications. Thus, artwork or "copy" alone will not fulfill the device master record requirements for labeling except for the most simplistic labeling such as brief errata sheets.

The engineering drawings or purchase specifications and mounting procedure must specify, as appropriate, the label substrate, dimensions, ink, finish, mounting method, etc., so that the purchased label will remain attached and legible during the customary conditions of processing, storage, handling, distribution, and use.

Front panels, other instrument panels, meters, fuses, pushbuttons, and the like often are labels or contain labels and must, as appropriate, meet GMP master record and control requirements. Component specifications, assembly drawings, and test/inspection procedures are appropriate GMP controls to prevent mixup of meters, pushbuttons, and other labeled instrument controls. Controls to prevent mixups are generally not needed for front and other instrument panels.

Whether a firm considers a software driven display to be labeling or data makes little difference under the GMP regulation, because either way, the finished device labeling or data must meet the device master record specifications. When firms develop and validate

TYPICAL SEQUENCE OF THE GMP CONTROL OF LABELS (TABLE 5.1)

PHASE	DEVICE TYPE		GMP SECTION (PART 820.)	CONTROL ACTIVITY
1. Development	NC*	C*	.120 & .100	Text review. Quality of mounting (rivets, adhesives, etc.). Quality of ink, anodize, etc. Content per 21 CFR 801, 807, 809, company claims and standards.
2. Evaluation	NC	C	.120	Simulated or actual processing (e.g., Sterilization), shipping tests, etc.
3. Documentation	NC	C	.181	Approve, date and change control label drawings.
		C	.121a	A key label must contain control number of finished device.
4. File Sample		C	.182b	Copy of actual label or artwork in the master record. See .181.
5. Procurement	NC	C	.120a	Proofread before release to inventory stock.
		C	.121b	Record signature of proofreader and date.
6. Storage	NC	C	.120d	Store labels so as to prevent mixups.
		C	.121c	Restrict access to labels to authorized persons.
7. Separate Operations	NC	C	.120b	Separate multiple operations to prevent mixups.
8. Area Inspection	NC	C	.120c	Before beginning labeling operations, designee to inspect area & remove extraneous devices & labels.
9. Issuance	NC	C	.120e	Examine for identity and, where appropriate, expiration date and control number. Record date and person examining labels.
10. Inspection	NC	C	.160	Inspect finished device per written procedure.
		C	.161	Designee must check all acceptance records & test results & see that records are present and complete.

* NC = Noncritical; C = Critical

software, they should also review these electronic displays to see that the "labeling" meets all applicable requirements, such as adherence to specifications in the master record, correct parameter identification, agreement with the instruction manual, and, of course, correct display of performance data.

When reviewing or auditing labeling operations, it is wise to keep in mind that the GMP regulation contains flexible requirements and thus allows flexibility in a quality assurance program. The degree of labeling control needed to satisfy the GMP regulation varies considerably for different devices and operations. In order to avoid wasting money and increasing the cost of health care, manufacturers need to give considerable and prudent thought to the appropriate level of control needed for their operations as allowed by 820.5. Information and guidelines presented in this chapter should aid manufacturers in making these decisions. The level of control needed should be reconsidered when products are added or changed. Likewise, the controls needed and success of the existing control program **must** be reviewed during QA system audits.

GENERAL DEVICE LABELING REQUIREMENTS

Label Integrity

All labels must be designed and applied to devices and containers so that the labels will remain in place and legible during the customary conditions of distribution, storage, and use. Likewise, other labeling such as user instructions should remain legible during customary storage and use. Note that 820.120(a) which states "Labels shall be designed, printed, and applied so as to remain legible..." refers to the actual design of the label and mounting method--not just testing or inspection of these to show that design requirements have been met. [Inspection is covered by the second sentence of 820.120(a), and by 820.120(e), 820.20(a), 820.80 and 820.160.] For example, labeling printed by machines onto plastic in vitro diagnostic media plates is sometimes smeared and thus is inadequate [FD&C 502(f)]. The manufacturers of such devices must assure that the print is legible and will remain legible until used.

Some magazines use "wet" ink which smears when touched by sweaty or oily fingers. Obviously, this type ink will not meet the GMP design requirements for package inserts, instruction manuals, etc.

Labels may be mounted by adhesives, screws, rivets, drive screws, etc., or printed or etched onto panels and/or onto controls. The labels should be located so that they will be seen but not be abraded during use. (Some of us have seen the unbelievable cases where safety labels on ladders and riding lawnmowers were placed in the foot rest areas. Of course, they were scrubbed off after a few uses!)

Receipt and Inspection

Upon receipt, all packaging and labeling materials, including preprinted containers, inserts, and preprinted packaging materials must be examined and, if deemed necessary by the company, tested to assure conformance with specifications. Also, samples of labels must be proofread by a designated individual(s). After being accepted by a responsible individual, these components may be placed into inventory or into production. These inspections must be recorded in the device history record as required by 820.80(a) and 820.120 to show that inspection and proofreading were performed. The inspection record for device labeling should be kept simple.

Area Separation and Inspection

All labeling and packaging operations should be separated to the degree necessary (820.5 and 820.40) to **make certain** there are no mixups between similar products or labels. Separation may be either a physical or spatial separation or by performing the labeling and packaging at different times for different devices. Separation is not required when mixups are impossible such as the case of labeled front panels that only fit the intended family of instruments (devices).

The likelihood of a labeling mixup determines how stringent production area controls should be. For example, label control need not be stringent if only dissimilar products and labeling are processed. Before beginning any packaging and labeling operation in which mixup could occur, the production area and equipment for the operation **must** be thoroughly examined to make certain that any devices and labeling materials remaining from previous operations have been removed. It is important to make certain that the surrounding area, tables, packaging lines, printing machines, and other equipment are cleared of labels and other materials used in the previous operation.

Unused labeling that contains pre-coded serial numbers, manufacturing date, expiration date, control number, etc., should be destroyed and not returned to the label storage area. The GMP regulation does not require reconciliation of the number of labels used versus the number issued, although this control is recommended for some devices, such as when different sizes of the same product are being packaged or otherwise labeled.

Storage

All printed packaging and labeling materials, including preprinted containers, inserts and preprinted packaging materials, **must** be stored in an area and manner suitable to prevent mixups (820.40, 820.120). Labeling should be identified and segregated to the degree necessary to prevent mixing of similar labeling. Access to labeling should be limited to authorized personnel.

Storage control should be appropriate for the number and kind of devices. For example, a firm that manufactures only one product with one label does not need an elaborately controlled storage area. Similarly, a firm with only a few types of devices having dissimilar labeling would not normally require stringent control.

One case that requires dedicated attention to storage and control is prelabeled "sterile" but "not-yet-sterilized" devices. Firms must make **absolutely certain** that mixups cannot occur. Also **make certain** that all such samples, if used for market promotion, are sterile or stamped with a manifest caution statement because a packaged and labeled market-promotion sample might be used by the recipient. Quality awareness training is required by Section 820.25 and marketing personnel must be informed of labeling control requirements and the consequences of a violation.

Label Check and Record

When issued for use, labeling **must** be carefully examined to make certain the contents of the labeling comply with the labeling specifications in the device master record for the specific device being produced. This examination **must** include any control numbers or expiration dates used on the labels. A record of this issuance check, including the date and name of the person performing the examination, **must** be made in the device history record.

If used, expiration dates **must** reflect the time after final packaging during which the device is fit for its intended use when stored and used per its labeling. The manufacturer should have stability test data which establishes the interval that the device remains fit for use.

If label mixups **cannot** occur--for example, a firm makes only one device or uses only one label--and there are no control numbers or expiration dates, the original inspection when the labeling was placed into inventory is an adequate check for compliance with the master record specifications. A second check need not be performed because it serves no purpose (820.5). If, however, there is any possibility that incorrect labeling can be used, a second check **must** be made when the labeling is issued for application, packaging, or shipping.

Changes

Labeling is part of the device master record; therefore, all changes to labeling **must** be made under a formal change control system similar to that required for specifications [820.100(a)(2)]. Any changes to labeling **must** be formally reviewed and authorized before implementation.

When making changes to primary aspects of a device and to primary documentation, the review group must determine if any secondary items such as labels or instructions are affected and also need changing. There should be a check-off block on change-order forms for recording that the effect of the primary change on labeling was considered and appropriate action was taken.

Relabeling and Over-labeling

Over-labeling by placing a new label over an old label is discouraged by FDA but is acceptable as long as the new label and its use meet GMP requirements (820.120, 820.115) for attachment, legibility, reprocessing, and change control. (Over-labeling is also discouraged in some foreign countries.)

ADDITIONAL LABELING REQUIREMENTS FOR CRITICAL DEVICES

Labeling for critical devices **must** meet the noncritical device labeling requirements and meet the three additional requirements in 820.121 as covered below.

Control Number

Critical device labeling **must** contain a control number, serial number, letters, etc., for traceability. This means a control number for the finished device, and not the label itself. Most labeling, however, also contains another number, such as a drawing number, for control of labeling configuration and procurement.

The control number for traceability need not be on every label on the device; however, the control number **must** appear on the unit label that goes to the ultimate user. The label on a shipping carton for bulk items does not meet this requirement because bulk items may go to a central distribution point in the user-facility and the shipping carton would most likely be discarded. In order to meet this traceability requirement, a label that would most likely reach the nurse or other user station **must** have the control number.

Proofreader's Signature

Before releasing labeling for critical devices to inventory, samples of labeling **must** be proofread as required for noncritical devices. In addition, the signature of the proofreader and the date of the proofreading **must** be recorded in the device history record.

Access Restriction

Access to labeling **must** be restricted to authorized personnel. Labeling also should be stored in an adequately segregated area to minimize the chance of mixups. Although the access requirement applies to labeling for critical devices, it is also recommended for labeling for noncritical devices because it increases the control over the label storage area with no significant increase in cost.

STERILE DEVICE LABELING

Special attention should be given to the labeling of sterile devices. Devices that are not sterile in their entirety (for example, sterility may be needed only for the lumen of certain devices) **must** be labeled to properly inform users what is actually intended to be "sterile" in the package. For example, a possible limiting statement might be:

"**Caution:** Only the fluid path of the set is sterile and nonpyrogenic. Do not use in a sterile or aseptic area without proper precautions."

Some devices are intended to be sterilized by the user before use. In this situation, the labeling should provide adequate information as to at least one suitable method of sterilization and any precautions or safeguards to be followed. For example, the labeling should describe any:

- special cleaning methods required;
- changes in the physical characteristics of the device that may result from reprocessing which affect its safety, effectiveness, or performance; and
- limit on the number of times resterilization and reuse can be done without affecting the safety or effectiveness of the device.

In the case of single-use sterile devices, some manufacturers include labeling to advise against resterilization and reuse. Some devices are simply not designed or constructed to be recleaned, and may not be capable of withstanding the necessary recleaning and resterilization procedures. Where reuse is common practice, manufacturers are encouraged to provide the information described in the above list.

The label of multi-device kits or packages containing a combination of sterile and nonsterile products **must** not state or imply that all contents are sterile.

The need for users to have instructions on how to open a sterile device package to avoid contamination of the device also needs to be evaluated, and when necessary, such instructions should be included in the labeling.

When a manufacturer modifies a device, the manufacturer must also review the labeling to make certain that it reflects current revisions and specifications. Some manufacturers identify labeling with a drawing number plus a revision code or date as an aid in identifying current labeling. The package insert or other labeling for in vitro diagnostic products is **required** to contain the revision date [21 CFR 809.10(b)(15)].

Shelf-life dating solely for package integrity and sterility is not usually required by FDA for general medical devices. There may be a need for expiration dating when a particular component of a device, such as a battery or diagnostic reagent, has a finite useful life. Labeling for in vitro diagnostic devices [809.10(a) and (b)] requires an expiration date or some other means by which users may be assured of quality at the time of use. This requirement applies to both sterile and nonsterile in vitro diagnostic devices.

Although not required by regulation, most manufacturers of complex devices and sterile devices voluntarily use lot or serial numbers for production control and, if the need arises, to expedite failure investigations, repairs, modifications, or recalls. Lot, batch, or other control numbers are required for:

- o critical devices (820.121);
- o some products subject to radiological health standards; and
- o in vitro diagnostic devices [809.10(a)(9)].

Adequate labeling for a medical device requires proper design and procurement of the labels and labeling. Design includes labeling content that meets the requirement of the GMP regulation as well as the needs of the customer. To achieve these goals a number of concepts must be kept in mind such as: writing to the reader, referring to the actual device in labeling, obvious identification of the controls used, etc.

CONTRACT STERILIZATION

Finished devices that are terminally sterilized by a firm other than the manufacturer pose a unique labeling problem. A common industry practice is to send the finished device in its final packaging to a contractor for sterilization. The final packaging is labeled as sterile even though the goods are unsterile during shipment from the manufacturer to the contractor. Specific restrictions apply in this instance, and a written agreement between the parties must be in effect [820.150(e)]. The requirements for the labeling of in process sterile goods in transit to the contract sterilizer are addressed in detail by Section 801.150, and covered previously under **Other Exemptions** in this booklet. Extreme care must be taken in this situation to eliminate the possibility of an unsterilized product being mistaken for a sterilized product. A firm should seriously consider the use of "visual indicator" labeling to distinguish between product before and after sterilization, e.g., the use of indicator tape with bands that develop color upon exposure to steam or ethylene oxide, or stick-on "dots" which change color upon exposure to radiation. Bear in mind that visual indicators will provide confidence that the product has been exposed to a sterilant and not that the product **is** sterile. A firm should also consider the use of dosimeters, i.e., a product that undergoes an irreversible change in physical or chemical properties that is proportional to the amount of exposure to a sterilant. Some contract sterilizers affix labeling to a contractor's product in the form of a sterilization number stamped upon the device container, or outer shipping containers. Firms who use the contract sterilizer's lot number as assurance that their devices have undergone sterilization should determine, via an audit of the facility if possible, that sterilization lot numbers are applied after, not before, being subject to sterilization.

Regulations on distribution are contained in 21 CFR 801, Subparts A and E; and GMP Sections 820.150, 820.160 and 820.161. Devices that have been sterilized, held, or shipped to the manufacturer's warehouse or other **controlled** distribution point before final release must be properly labeled. The pallets, or designated unit, must be marked to indicate the status of the device such as "sterilized: awaiting test results," or an equivalent statement. The company must be able to show that it has control of the devices until final release and, if necessary, could have them destroyed or returned for reprocessing. For this reason, a distributor's warehouse or facility is not considered a controlled distribution point.

RADIATION-EMITTING DEVICE LABELING

INTRODUCTION

Labeling of radiation-emitting products applies to medical devices; all products which emit ionizing, or nonionizing electromagnetic or particulate radiation; and products which emit sonic, infrasonic, or ultrasonic radiation as the result of operation of an electronic circuit. Radiation-emitting devices include products that emit radiation either by design (e.g., X-ray equipment) or as a consequence of operation (e.g., television set), but exclude products that emit radiation as a result of the decay of a radioactive element or isotope (e.g., an ionization type smoke detector). Section 358 of the Radiation Control for Health and Safety Act (RCHSA) of 1968 authorizes the development of Federal standards for these types of radiation producing products. These standards are contained within the regulations listed under 21 CFR Part 1000. The corresponding regulations are listed by product type in subsequent headings of this section. This booklet will cover only those portions of these standards related to product labeling and will not attempt to address technical specifications contained in the standards. Thus, the nature and placement of labeling may vary from those previously discussed under **General Device Labeling;** however, the concepts of "label" and "labeling" remain the same, e.g., the "label" of 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 related to high voltages and X-ray shielding.

At the present time, as a matter of choice and practicality, FDA does not choose to actively regulate some common household products such as radios and incandescent light bulbs; however, if such products were found to pose a consumer hazard, the FDA could choose to regulate them. A good example of a hazard to consumers is the cordless telephone. As a result of consumer complaints, and confirmed injuries due to the placement, volume, and frequencies of ringers in certain brands of telephones, FDA set and enforced guidelines to prevent hearing injuries.

This section will cover labeling of radiation-emitting medical and other electronic devices. Due to the amount of technical data contained in the corresponding sections of the CFR, reprints of the CFR sections pertaining to laser labeling will be used where appropriate to demonstrate format requirements. Numbers appearing in parentheses next to subject headings are the corresponding sections of 21 CFR.

GENERAL LABELING REQUIREMENTS FOR ELECTRONIC PRODUCTS (1010.3)

Manufacturers of electronic products covered under a performance standard shall provide the following information on a tag or label permanently affixed or inscribed on the product. The following information should be readily viewable when the product is fully assembled:

- o The full name and address of the manufacturer of the product.
  - Alternately, the product can contain the full name and address of a company or individual other than the manufacturer, provided that the full name and address of the actual manufacturer has been previously identified to the Director of the Center for Devices and Radiological Health (CDRH). (This alternative is necessary so that CDRH can identify manufacturers of particular models of devices in those instances where the listed distributor uses different manufacturers for each model.)
  - Abbreviations such as Co., Inc., or their foreign equivalents, and the initials of the first and middle names of individuals may be used.
- o The place and month and year of manufacture.
  - The place of manufacture may be expressed in a code if the code has been previously supplied to the Director of CDRH.
  - The month and year of manufacture cannot be coded or abbreviated. The month and a four digit number for the year must appear as follows:
    "MANUFACTURED: (Insert Month and Year of Manufacture)"

In a case where it is not feasible to affix identification labeling in accordance with the above, the Director of CDRH may approve an application for an alternate means of identification.

The manufacturer must furnish the Director of CDRH with a complete listing of all brand names and the names and addresses of the individuals or companies for which electronic products are manufactured under a standard.

Electronic products intended for United States Government use may be exempted from the above upon application to the Director of CDRH by the manufacturer, assembler, or a U.S. department or agency.

All products intended solely for export shall be labeled or tagged to show that they are intended for export.

The manufacturer of any electronic product covered by an exemption from performance standards (i.e., standards, other than labeling, which are not covered in this chapter) must permanently attach a tag or label stating:

"This electronic product has been exempted from the Food and Drug Administration radiation safety performance standards prescribed in the Code of Federal Regulations, Title 21, Chapter I, Subchapter J, pursuant to Exemption No.__, Granted on _____."

IONIZING RADIATION-EMITTING PRODUCTS

Television Receivers (1020.1)

A television receiver is an electronic product designed to receive and display a television picture through broadcast, cable, or closed circuit television. Digital monitors which display a fixed (non-moving) image, e.g., computer screens, are excluded from the standard.

- o Any receiver capable of producing radiation in excess of the standard through component failure or improper adjustment shall have a permanently affixed or inscribed warning label listing the high voltage specification and instructions for adjusting the high voltage to the specified value.

Cold-cathode Gas Discharge Tubes (1020.20)

Cold-cathode discharge tubes are devices designed to demonstrate the effects of a flow of electrons or the production of X-rays.

- o Manufacturers shall provide applicable safety instructions, instructions for use, and power source specifications for each tube.
  - Each enclosure or tube shall have permanently affixed polarity identification of the terminals.
  - Tubes designed for heat, fluorescence, or magnetic effect must have a warning indicating that excess power application may result in x-radiation.
  - Tubes designed for x-radiation must bear a warning that the device produces X-rays when energized.
- o The required tags or labels must be visible when the device is fully assembled for use.

Diagnostic X-ray Systems (1020.30)

Diagnostic X-ray systems incorporate one or more certified components.Certified components are X-ray system components manufactured after certain dates listed in 21 CFR 1020.30(a)(i). Both diagnostic X-ray systems and computed tomography X-ray systems manufactured before November 29, 1984, are subject to the following requirements:

- o The control panel containing the main power switch shall have a statement reading: **"WARNING: This X-ray unit may be dangerous to patient and operator unless safe exposure factors and operating instructions are observed."**
- o Temporarily installed compatible components must bear the following labeling: **"Temporarily Installed Compatible Component.** This certified component has been assembled, installed, adjusted, and tested by me according to the instructions provided by the manufacturer. Signature; Company Name; Street Address, City, State, Zip Code, and Date of Installation."

- Temporarily installed noncompatible components must bear the following labeling: "**Temporarily Installed Noncompatible Component.** This certified component has been assembled or installed by me, but could not be assembled, installed, adjusted, and tested by me according to the instructions provided by the manufacturer because other already existing components of the system do not meet the compatibility specifications of the certified component being installed, and there are no commercially available certified components of a similar type that are compatible with the system. Signature, Company Name, Street Address, City, State, Zip Code, and Date of Installation."

Radiographic Equipment (1020.31)

- If the device has the capability of overriding the positive beam limitation (PBL) in case of system failure, the override key or switch shall be labeled: "FOR X-RAY FIELD LIMITATION SYSTEM FAILURE."

- If the device has the capability of overriding the automatic X-ray field size adjustment in case of system failure, the override switch shall be labeled: "FOR X-RAY FIELD LIMITATION SYSTEM FAILURE."

Fluoroscopic Equipment (1020.32)

- If the device has the capability of overriding the automatic X-ray field size adjustment in case of system failure, the override switch shall be labeled: "FOR X-RAY FIELD LIMITATION SYSTEM FAILURE."

Cabinet X-ray Systems (1020.40)

- At least one indicator shall be visible from each door, access panel and port, and labeled: "X-RAY ON."

- If a cabinet X-ray system is designed to admit humans, it must bear the following additional labeling:

  - Any controls which can be used to initiate X-ray generation must be labeled:

    "CAUTION: X-RAYS PRODUCED WHEN ENERGIZED"

  - Each port shall have a clearly visible label stating:

    "CAUTION: DO NOT INSERT ANY PART OF THE BODY WHEN SYSTEM IS ENERGIZED - X-RAY HAZARD."

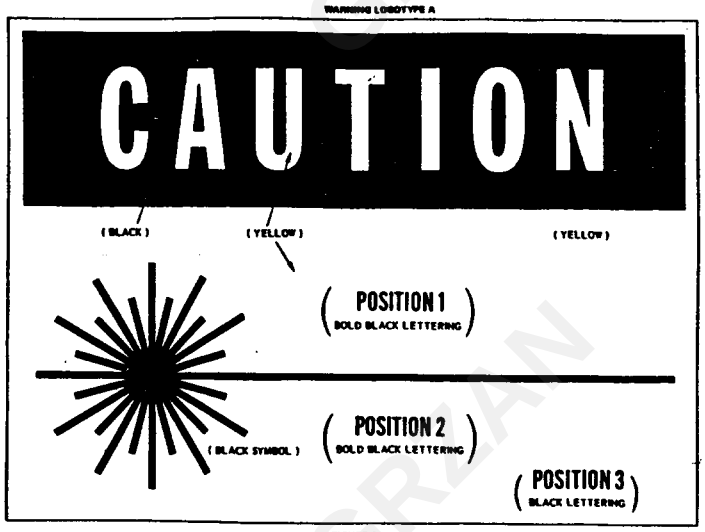
LIGHT-EMITTING PRODUCTS

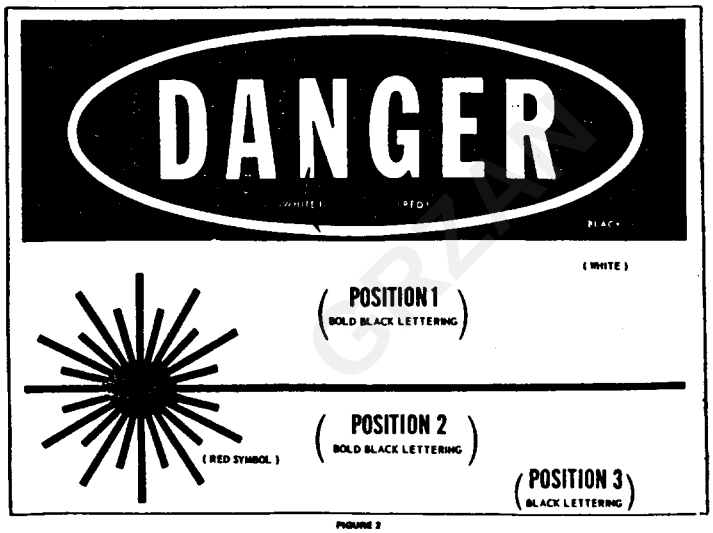
Lasers (1040.10)

Lasers are devices capable of producing intense radiation at a specific wavelength both for medical and industrial purposes. In addition to the general labeling requirements for firm name, street address, state, and zip code, lasers require labeling specific to their type, class, wavelength, and power output. Due to the numerous combinations of

labeling types dictated by class, wavelength, and power output, it would not be practical to cover each in specific detail in this booklet. Instead, use the following sample label types in conjunction with the following reprints of CFR sections to demonstrate specific labeling requirements.

SAMPLE LASER LABELS





(g) *Labeling requirements.* In addition to the requirements of §§ 1010.2 and 1010.3, each laser product shall be subject to the applicable labeling requirements of this paragraph.

(1) *Class IIa and II designations and warnings.* (i) Each Class IIa laser product shall have affixed a label bearing the following wording: "Class IIa Laser Product—Avoid Long-Term Viewing of Direct Laser Radiation."

(ii) Each Class II laser product shall have affixed a label bearing the warning logotype A (Figure 1 in this paragraph) and including the following wording:

[Position I on the logotype]

"LASER RADIATION—DO NOT STARE INTO BEAM"; and

[Position 3 on the logotype]

"CLASS II LASER PRODUCT".

(2) *Class IIIa and IIIb designations and warnings.* (i) Each Class IIIa laser product with an irradiance less than or equal to 2.5×10^{-3} W cm^{-2} shall have affixed a label bearing the warning logotype A (Figure 1 of paragraph (g)(1)(ii) of this section) and including the following wording:

[Position 1 on the logotype]

"LASER RADIATION—DO NOT STARE INTO BEAM OR VIEW DIRECTLY WITH OPTICAL INSTRUMENTS"; and,

[Position 3 on the logotype]

"CLASS IIIa LASER PRODUCT".

(ii) Each Class IIIa laser product with an irradiance greater than 2.5×10^{-3} W cm^{-2} shall have affixed a label bearing the warning logotype B (Figure 2 in this paragraph) and including the following wording:

[Position 1 on the logotype]

"LASER RADIATION—AVOID DIRECT EYE EXPOSURE"; and,

[Position 3 on the logotype]

"CLASS IIIa LASER PRODUCT".

(iii) Each Class IIIb laser produ shall have affixed a label bearing the warning logotype B (Figure 2 of paragraph (g)(2)(ii) of this section) and including the following wording:

[Position 1 on the logotype]

"LASER RADIATION—AVOID DIRECT EXPOSURE TO BEAM"; and,

[Position 3 on the logotype]

"CLASS IIIb LASER PRODUCT".

(3) *Class IV designation and warning.* Each Class IV laser product shall have affixed a label bearing the warning logotype B (Figure 2 of paragraph (g)(2)(ii) of this section), and including the following wording:

[Position 1 on the logotype]

"LASER RADIATION—AVOID EYE OR SKIN EXPOSURE TO DIRECT OR SCATTERED RADIATION"; and,

[Position 3 on the logotype]

"CLASS IV LASER PRODUCT".

(4) *Radiation output information on warning logotype.* Each Class II, III, and IV laser product shall state in appropriate units, at position 2 on the required warning logotype, the maximum output of laser radiation, the pulse duration when appropriate, and the laser medium or emitted wavelength(s).

(5) *Aperture label.* Each laser product, except medical laser products and Class IIa laser products, shall have affixed, in close proximity to each aperture through which is emitted accessible laser or collateral radiation in excess of the accessible emission limits of Class I and Table VI of paragraph (d) of this section, a label(s) bearing the following wording as applicable.

(i) "AVOID EXPOSURE—Laser radiation is emitted from this aperture," if the radiation emitted through such aperture is laser radiation.

(ii) "AVOID EXPOSURE—Hazardous electromagnetic radiation is emitted from this aperture," if the radiation emitted through such aperture is collateral radiation described in Table VI, item 1.

(iii) "AVOID EXPOSURE—Hazardous x-rays are emitted from this aperture," if the radiation emitted through such aperture is collateral radiation described in Table VI, item 2.

(6) *Labels for noninterlocked protective housings.* For each laser product, labels shall be provided for each portion of the protective housing which has no safety interlock and which is designed to be displaced or removed during operation, maintenance, or service, and thereby could permit human access to laser or collateral radiation in excess of the limits of Class I and Table VI. Such labels shall be visible on the protective housing prior to displacement or removal of such portion of the protective housing and visible on the product in close proximity to the opening created by removal or displacement of such portion of the protective housing, and shall include the wording:

(i) "CAUTION—Laser radiation when open. DO NOT STARE INTO BEAM." for Class II accessible laser radiation.

(ii) "CAUTION—Laser radiation when open. DO NOT STARE INTO BEAM OR VIEW DIRECTLY WITH OPTICAL INSTRUMENTS." for Class IIIa accessible laser radiation with an irradiance less than or equal to 2.5×10^{-3} W cm^{-2}.

(iii) "DANGER—Laser radiation when open. AVOID DIRECT EYE EXPOSURE." for Class IIIa accessible laser radiation with an irradiance greater than 2.5×10^{-3} W cm^{-2}.

(iv) "DANGER—Laser radiation when open. AVOID DIRECT EXPOSURE TO BEAM." for Class IIIb accessible laser radiation.

(v) "DANGER—Laser radiation when open. AVOID EYE OR SKIN EXPOSURE TO DIRECT OR SCATTERED RADIATION." for Class IV accessible laser radiation.

(vi) "CAUTION—Hazardous electromagnetic radiation when open." for collateral radiation in excess of the accessible emission limits in Table VI, item 1 of paragraph (d) of this section.

(vii) "CAUTION—Hazardous x-rays when open." for collateral radiation in excess of the accessible emission limits in Table VI, item 2 of paragraph (d) of this section.

(7) *Labels for defeatably interlocked protective housings.* For each laser product, labels shall be provided for each defeatably interlocked (as described in paragraph (f)(2)(iv) of this section) portion of the protective housing which is designed to be displaced or removed during operation, maintenance, or service, and which upon interlock defeat could permit human access to laser or collateral radiation in excess of the limits of Class I or Table VI. Such labels shall be visible on the product prior to and during interlock defeat and in close proximity to the opening created by the removal or displacement of such portion of the protective housing, and shall include the wording:

(i) "CAUTION—Laser radiation when open and interlock defeated. DO NOT STARE INTO BEAM." for Class II accessible laser radiation.

(ii) "CAUTION—Laser radiation when open and interlock defeated. DO NOT STARE INTO BEAM OR VIEW DIRECTLY WITH OPTICAL INSTRUMENTS." for Class IIIa accessible laser radiation with an irradiance less than or equal to 2.5×10^{-3} W cm^{-2}.

(iii) "DANGER—Laser radiation when open and interlock defeated. AVOID DIRECT EYE EXPOSURE." for Class IIIa accessible laser radiation when an irradiance greater than 2.5×10^{-3} W cm^{-2}.

(iv) "DANGER—Laser radiation when open and interlock defeated. AVOID DIRECT EXPOSURE TO BEAM." for Class IIIb accessible laser radiation.

(v) "DANGER—Laser radiation when open and interlock defeated. AVOID EYE OR SKIN EXPOSURE TO DIRECT OR SCATTERED RADIATION." for Class IV accessible laser radiation.

(vi) "CAUTION—Hazardous electromagnetic radiation when open and interlock defeated." for collateral radiation in excess of the accessible emission limits in Table VI, item 1 of paragraph (d) of this section.

(vii) "CAUTION—Hazardous x-rays when open and interlock defeated." for collateral radiation in excess of the accesible emission limits in Table VI, item 2 of paragraph (d) of this section.

(8) *Warning for visible and/or invisible radiation.* On the labels specified in this paragraph, if the laser or collateral radiation referred to is:

(i) Invisible radiation, the word "invisible" shall appropriately precede the word "radiation"; or

(ii) Visible and invisible radiation, the words "visible and invisible" or "visible and/or invisible" shall appropriately precede the word "radiation."

(iii) Visible laser radiation only, the phrase "laser light" may replace the phrase "laser radiation."

(9) *Positioning of labels.* All labels affixed to a laser product shall be positioned so as to make unnecessary, during reading, human exposure to laser radiation in excess of the accessible emission limits of Class I radiation or the limits of collateral radiation established to Table VI of paragraph (d) of this section.

(10) *Label specifications.* Labels required by this section and § 1040.11 shall be permanently affixed to, or inscribed on, the laser product, legible, and clearly visible during operation, maintenance, or service, as appropriate. If the size, configuration, design, or function of the laser product would preclude compliance with the requirements for any required label or would render the required wording of such label inappropriate or ineffective, the Director, Office of Compliance (HFZ-300), Center for Devices and Radiological Health, on the Director's own initiative or upon written application by the manufacturer, may approve alternate means of providing such label(s) or alternate wording for such label(s) as applicable.

(h) *Informational requirements*—(1) *User information.* Manufacturers of laser products shall provide as an integral part of any user instruction or operation manual which is regularly supplied with the product, or, if not so supplied, shall cause to be provided with each laser product:

(i) Adequate instructions for assembly, operation, and maintenance, including clear warnings concerning precautions to avoid possible exposure to laser and collateral radiation in excess of the accessible emission limits in Tables I, II-A, II, III-A, III-B, and VI of paragraph (d) of this section, and a schedule of maintenance necessary to keep the product in compliance with this section and § 1040.11.

(ii) A statement of the magnitude, in appropriate units, of the pulse durations(s), maximum radiant power and, where applicable, the maximum radiant energy per pulse of the accessible laser radiation detectable in each direction in excess of the accessible emission limits in Table I of paragraph (d) of this section determined under paragraph (e) of this section.

(iii) Legible reproductions (color optional) of all labels and hazard warnings required by paragraph (g) of this section and § 1040.11 to be affixed to the laser product or provided with the laser product, including the information required for positions 1, 2, and 3 of the applicable logotype (Figure 1 of paragraph (g)(1)(ii) or Figure 2 or paragraph (g)(2)(ii) of this section). The corresponding position of each label affixed to the product shall be indicated or, if provided with the product, a statement that such labels could not be affixed to the product but were supplied with the product and a statement of the form and manner in which they were supplied shall be provided.

(iv) A listing of all controls, adjustments, and procedures for operation and maintenance, including the warning "Caution—use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure."

(v) In the case of laser products other than laser systems, a statment of the compatibility requirements for a laser energy source that will assure compliance of the laser product with this section and § 1040.11.

(vi) In the case of laser products classified with a 7 millimeter diameter aperture stop as provided in paragraph (e)(3)(i) of this section, if the use of a 50 millimeter diameter aperture stop would result in a higher clsssification of the product, the following warning shall be included in the user information: "CAUTION—The use of optical instruments with this product will increase eye hazard."

(2) *Purchasing and servicing information.* Manufacturers of laser products shall provide or cause to be provided:

(i) In all catalogs, specification sheets, and descriptive brochures pertaining to each laser product, a legible reproduction (color optional) of the

class designation and warning required by paragraph (g) of this section to be affixed to that product, including the information required for positions 1, 2, and 3 of the applicable logotype (Figure 1 of paragraph (g)(1)(ii) or Figure 2 of paragraph (g)(2)(ii) of this section).

(ii) To servicing dealers and distributors and to others upon request at a cost not to exceed the cost of preparation and distribution, adequate instructions for service adjustments and service procedures for each laser product model, including clear warnings and precautions to be taken to avoid possible exposure to laser and collateral radiation in excess of the accessible emission limits in Tables I, II-A, II, III-A, III-B, and VI of paragraph (d) of this section, and a schedule of maintenance necessary to keep the product in compliance with this section and § 1040.11; and in all such service instructions, a listing of those controls and procedures that could be utilized by persons other than the manufacturers or the manufacturer's agents to increase accessible emission levels of radiation and a clear description of the location of displaceable portions of the protective housing that could allow human access to laser or collateral radiation in excess of the accessible emission limits in Tables I, II-A, II, III-A, III-B, and VI of paragraph (d) of this section. The instructions shall include protective procedures for service personnel to avoid exposure to levels of laser and collateral radiation known to be hazardous for each procedure or sequence of procedures to be accomplished, and legible reproductions (color optional) of required labels and hazard warnings.

(i) *Modification of a certified product.* The modification of a laser product, previously certified under § 1010.2, by any person engaged in the business of manufacturing, assembling, or modifying laser products shall be construed as manufacturing under the act if the modification affects any aspect of the product's performance or intended function(s) for which this section and § 1040.11 have an applicable requirement. The manufacturer who performs such modification shall recertify and reidentify the product in accordance with the provisions of §§ 1010.2. and 1010.3.

(The information collection requirements contained in paragraph (a)(3)(ii) were approved by the Office of Management and Budget under control number 0910-0176)

[50 FR 33688, Aug. 20, 1985; 50 FR 42158, Oct. 18, 1985]

§ 1040.11 Specific purpose laser products.

(a) *Medical laser products.* Each medical laser product shall comply with all of the applicable requirements of § 1040.10 for laser products of its class. In addition, the manufacturer shall:

(1) Incorporate in each Class III or IV medical laser product a means for the measurement of the level of that laser radiation intended for irradiation of the human body. Such means may have an error in measurement of no more than 20 percent when calibrated in accordance with paragraph (a)(2) of this section. Indication of the measurement shall be in International System Units. The requirements of this paragraph do not apply to any laser radiation that is all of the following:

(i) Of a level less than the accessible limits of Class IIIa; and

(ii) Used for relative positioning of the human body; and

(iii) Not used for irradiation of the human eye for ophthalmic purposes.

(2) Supply with each Class III or IV medical laser product instructions specifying a procedure and schedule for calibration of the measurement system required by paragraph (a)(1) of this section.

(3) Affix to each medical laser product, in close proximity to each aperture through which is emitted accessible laser radiation in excess of the accessible emission limits of Class I, a label bearing the wording: "Laser aperture."

(b) *Surveying, leveling, and alignment laser products.* Each surveying, leveling. or alignment laser product shall comply with all of the applicable requirements of § 1040.10 for a Class I, IIa, II or IIIa laser product and shall not permit human access to laser radiation in excess of the accessible emission limits of Class IIIa.

(c) *Demonstration laser products.* Each demonstration laser product shall comply with all of the applicable requirements of § 1040.10 for a Class I, IIa, II, or IIIa laser product and shall not permit human access to laser radiation in excess of the accessible emission limits of Class I and, if applicable, Class IIa, Class II, or Class IIIa.

[50 FR 33702, Aug. 20, 1985]

Sunlamp Products and Ultraviolet Lamps (1040.20)

Lamps that produce ultraviolet radiation with wavelengths in air between 200 and 400 nanometers which are designated as sunlamp products or ultraviolet lamps intended for use in sunlamp products are subject to the requirements of 1040.20.

All labels are to be affixed or inscribed on an exterior surface that can be easily seen by the person being exposed immediately before use of the product.

Sunlamp Products

- o Each sunlamp product shall have label(s) with the warning statement: "DANGER-Ultraviolet radiation. Avoid overexposure. As with natural sunlight, overexposure can cause eye and skin injury and allergic reactions. Repeated exposure may cause premature aging of the skin and skin cancer. **Wear Protective Eyewear; Failure to May Result in Severe Burns or Long Term Injury to the Eyes.** Medications or cosmetics may increase your sensitivity to the ultraviolet radiation. Consult physician before using sunlamp if you are using medications or have a history of skin problems or believe yourself especially sensitive to sunlight. If you do not tan in the sun, you are unlikely to tan from use of this product."

  In addition the label must also contain:

  - Recommended exposure positions;
  - Directions for achieving the recommended exposure positions;
  - A recommended exposure schedule;
  - A statement of the amount of time it may take for the expected results to appear;
  - A designation of the ultraviolet lamp type to be used in the product; and
  - Reproductions of the required labeling are to be prominently displayed at the beginning of the product instruction manual.

Ultraviolet Lamps

- o Labels for ultraviolet lamps require the following:
  - The words: "Sunlamp - DANGER - Ultraviolet radiation. Follow instructions;"
  - The model identification; and
  - The words: "Use ONLY in fixtures equipped with a timer."

ULTRASONIC RADIATION-EMITTING DEVICES

Ultrasonic Therapy Products (1050.10)

In addition to the general labeling requirements, ultrasonic therapy products are subject to the following additional labeling requirements:

- o Operation controls--identification of operator control functions;
- o Service controls--identification of the service control functions plus the statement "For service adjustment only;"
- o Generators--generator labels shall state the brand name, model designation, serial number or other unique identification, ultrasonic frequency, and type of waveform;
- o Applicators--applicator labels shall state the brand name, model designation, and serial number or other unique identification; the generator for which the applicator is intended; and the ultrasonic frequency, effective radiating area, maximum beam nonuniformity ratio, and type of applicator.
- o Manuals--user instruction or operator manuals shall contain:
  - assembly, operation, safe use, safety procedures and precautions, and a maintenance schedule;
  - description of the special distribution of the ultrasonic radiation field and the orientation of the field with respect to the applicator;
  - description of the uncertainties in magnitude of various parameters relative to the ultrasonic energy; and
  - a listing of controls, adjustments, and procedures for operation and maintenance including a warning: "Caution: Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous exposure to ultrasonic energy."

GOVERNMENT CONTRACT DEVICE LABELING REQUIREMENTS

INTRODUCTION

Agencies of the U.S. Government such as the Department of Defense and the Veterans Administration are major purchasers, users, and warehousers of medical equipment. Large stockpiles of medical equipment are maintained in warehouses located throughout the country. In addition to working stock drawn by the military services, reserves are needed to maintain a state of war preparedness. Their varied needs and the logistics of distribution necessitate extraordinary packaging and labeling requirements. For example, supplies of hemostatic forceps must be readily available for immediate shipment, or use after prolonged storage, anywhere in the world, which includes dry desert, humid jungle environments, or sub-zero Arctic conditions. In addition, the method of transport could include dropping from an airplane, or floating the supplies to shore. FDA requirements for labeling, size, and placement are not enough; labeling must be appropriately saltwater proof and fade resistant, and may even include camouflage markings. In order to assure conformity with their needs, the U.S. Government has established military standards, or specifications, for about every imaginable piece of equipment including hardware, electronics, and medical equipment.

LABELING SPECIFICATIONS MIL-STD-129H

MIL-STD-129H is the most commonly used labeling standard for U.S. Government medical equipment purchases. This document is generally not a stand alone specification, but rather is used in conjunction with the device specification. For example, the military specification for a radiographic grid (known as #GG-G-00650a, Grid, Radiographic, Straight, Wafer Type) contains a heading entitled "Labeling Specifications." The labeling specifications listed call for Fed Std No. 123 (essentially a commercial package) for civilian agencies such as the General Services Administration, and requires MIL-STD-129H for the military services. When filling a Government contract these specifications take precedence over FDA requirements.

The number, size, placement, and color of the labeling would be specified in the the product specification by referring to the appropriate section of MIL-STD-129H.

The interior or unit label and exterior or shelf package label requirements contained in MIL-STD-129H are as follows:

- o NSN/NATO stock number (National Serial Number)--a unique number assigned to a specific product type, regardless of manufacturer;
- o Manufacturer's part number (when specifically required by the contract);
- o Item description (as specified in the contract);
- o Quantity and unit of issue;
- o Contract, purchase, or delivery order number; and
- o Level of protection and date preservation was applied.

The outer packaging requirements are:

- o NSN/NATO stock number;
- o Manufacturer's part number;
- o Item description (as specified in the contract);
- o Gross weight and volume in cubic feet;
- o Level of protection and date preservation was applied;
- o Proper shipping names (for hazardous items only);
- o Contract, purchase order, or delivery order number; and
- o Name, address, and zip code of prime contractor;
- o LOGMARS*

* On 7/1/82 the Department of Defense had amended MIL-STD-129H to include a requirement for LOGMARS (Logistics Application of Automated Marking and Reading Symbology) on device labels. This labeling is the same form as the UPC (Universal Product Code) or bar code which has become an integral part of consumer items. LOGMAR labeling includes a series of digitally encoded lines containing the NSN and contract number.

DEVELOPMENT OF DEVICE LABELING

INTRODUCTION

Labeling is very important to medical device firms because there is often a direct relationship between device misuse and the labeling, especially in the directions for use. In many cases the labeling may meet the requirements of the regulations; but it may fail to fully take into consideration the user needs, possible uses other than that indicated, or other factors that may contribute to misuse of the device.

It is significant that approximately 40% of Mandatory Device Reporting (MDR) filings involve user error. FDA, the medical device industry, and the users must become more aware of this situation and work together to resolve it. One of the problem areas is labeling. In addition to the cases where there is a primary association between labeling and MDR reports, labeling can also be an "underlying" or secondary cause of misuse that leads to MDR reports.

There are three general problem areas with labeling that FDA has encountered:

Misbranding - The failure of the labeling to meet the requirements of the labeling regulations. This includes misleading statements, inadequate directions for use, or the exclusion of warning statements or contraindications;

Poor Labeling Control - This situation occurs during the manufacturing process due to a failure in the quality assurance or GMP program. Poor labeling controls result in incorrect activities such as a "mixup" in the labeling for different devices, the use of outdated labeling, or the improper application of the labeling to the device; and

Inadequate Labeling - Labeling that does not constitute misbranding but could be improved to prevent misuse or mishandling of the device.

The first two points, **misbranding,** and **poor label control** violate the letter of the law. The last, **inadequate labeling,** or **labeling that is less than it can or should be**, may not always violate the law, but can result in problems which the law was designed to prevent. Previous sections in this chapter have addressed two aspects of device labeling necessary to comply with the law. The first section in this chapter discusses the definition and causes of misbranding; the second section (Section 5) discusses areas of poor label control as addressed in the medical device GMP's. This section will address inadequate labeling and concentrate on techniques for generating and presenting text that is easy to read. It will also cover how to correlate text with figures, and how to correlate text with the device.

LABELING PROBLEMS

Two of the most important aspects to consider in labeling devices is to be cognizant of WHO will be using the device and HOW it is to be used. Once this is realized, suitable labeling can be drafted.

Often we have heard stories of parents unable to assemble "easy-to-assemble" toys on Christmas eve. Identical products with identical labeling (the instructions) may have other than the same results after assembly. Why? Because the manufacturer had failed to consider WHO. The instructions had been written at the level of someone moderately skilled in mechanics, whereas some assemblers might be confused by the operation of an electric drill. How could the problem be corrected? By the use of labeling! A simple way would be

to change the labeling to read "difficult-to-assemble;" however, this might well have a negative impact on sales. The proper way, as we'll cover later, would be to draft a detailed set of instructions, using pictorials where necessary, directed at the expected experience level of the purchaser.

A manufacturer of aluminum porch awnings in Florida had been successfully marketing his product locally for over 20 years. He obtained capital and expanded his operations along the Eastern Seaboard. Soon he began to receive numerous complaints of awning collapse from the Northeast. Why? Because he failed to consider HOW. The method of attachment recommended in the instructions was insufficient to hold the added weight of predictable northeastern snowfall. In a manner similar to the above problem, the solution could be to either restrict sales to states below in the Sunbelt, or to provide an explanation and a pictorial that detailed a method of securing the awning properly to support the expected additional weight.

The same arguments hold true for medical devices whether they be catheters, heart valves, or in vitro diagnostic products. Labeling not only can be used to assure proper use of the device, but can be used to compensate for design deficiencies or alert the user to abnormal conditions.

A firm who marketed an external rigid splint began to receive reports from hospitals that patients had suffered burns and blistering on limbs where the splint had been applied. The splint consists of a coated fabric sandwiched between polymeric film and foam. In use, the foam side is placed against the limb. Water is then applied to initiate a chemical polymerization which releases heat and causes the splint to become rigid.

The label on the splint read: "**Place Opposite Side on Limb.**" In one hospital personnel stated that the label had been improperly placed on the limb side of the splint. As a result, the patients limbs were burned during the polymerization reaction. It was then discovered by the firm that some lots had the label on the wrong side of the splint, and these lots were associated with the hospitals' complaints.

In fact, this entire sequence of events probably could have been avoided by proper label content. The phrase "**Place Opposite Side on Limb**" is an ambiguous statement and does not identify any component of the splint. A more helpful descriptive statement would state:

> **"Place the (insert color, texture, etc.) Film on Outside, Away from Limb. Caution: Film Gets Hot!"**

A positive statement with the film identified by color or texture would tend to reinforce the instructions for proper placement of the label during manufacture, and placement of the splint during use on the limb.

Let's take another look at the original labeling on the splint: "Place Opposite Side on Limb." Note the geometric term, "side." In general, be very careful when using top, side, end, bottom, edge, and other geometric terms in labeling as these are often ambiguous. Always make sure the intent is obvious when the user is looking at the device.

REDUCING LABELING PROBLEMS

Adequate labeling for a medical device requires proper design of labeling, controlled procurement of the labels and labeling, and proper application of labeling. Design includes labeling content that meets the requirement of the GMP regulation **as well as the needs of the user.** One should emphasize the second point: **needs of the user.** To help meet the needs of the user, there are some basic guidelines, rules, and practices that can be used to immediately improve the writing of labels and instructions.

Writers are encouraged to obtain a copy of 40,000 Words or a similarly titled book by any of the reference-book publishing companies. Most of these reference books have about four pages of punctuation rules. Using the four small pages of rules can immediately improve your writing. For example, you can avoid the common punctuation error of not using semi-colons to replace commas when needed. Also, one should obtain and use a standard college-level text on technical writing.

Further, to achieve our goals a number of concepts must be kept in mind such as: writing to the reader, referring to the actual device in labeling, obvious identification of the controls used, etc. Following is a review of these points with emphasis on how they can be used to make labeling clear and comprehensible.

Write to Reader

The most serious problem is that writers tend to write to themselves. Their material is clear to them--and they mistakenly think it is as clear to others. For example, the sensitivity control on an instrument is called: "gain" control on page one of the instruction manual, "amplitude" control on page two, and "level" control in the next section. Further, the photograph in the **Introduction** shows the same control with a call-out labeled "Signal Adjust". No wonder readers are confused! Yet the author of the example knew what he was trying to write about and, most certainly, he was writing to himself.

For some devices such as home-use devices, it may be necessary to determine the reading level of the intended users.

Refer to Actual Device

One simple way to reduce control identity confusion as described above, reduce other types of labeling errors, and increase clarity is for authors to keep a labeled instrument, kit, or photograph(s) nearby and refer to it as they write. It is easier to write the truth when you know the truth. Make sure the terminology and descriptions in the labeling matches that on the device. Always use the same title for each given item or control throughout the manual, insert, label, or advertisement. Likewise, the same title should be used in charts, figures, or screen displays such as cathode-ray tubes, etc. Remember to:

- write to your intended readers;
- write with a labeled device or photographs in sight; and
- use consistent titles.

Obvious Identification of Controls

Because the title of controls or other items on labels and screen displays **should be exactly the same** as in the labels on equipment, reagents, accessories, etc., authors may need to develop and use an appropriate correlation technique for corresponding titles in instruction manuals, package inserts, etc. One common technique is to use all capitals for the titles of controls in labeling. For example:

Flip the POWER switch to ON.
Press the HEAT button to switch the heater on.
In about three seconds, the READY lamp will illuminate.

With this correlation technique, the words "on" and "off" are capitalized in the labeling only when they actually appear on the instrument control panel. Note that "ON" is capitalized in "POWER switch to ON" as the actual switch has "POWER", "ON", and "OFF" printed by it. In contrast, note that "on" would not be capitalized in the example "to switch the heater on" as it is not a label of a control on the device. Also, be careful to use a simple correlation system for names of controls that is readily apparent to the intended reader.

Don't Distract Reader

Readers are very busy trying to learn how to use a new device. They should not be annoyed by any unnecessary distractions such as:

- changes in format;
- unusual typeface;
- incorrect page numbers, and
- incorrect figure numbers.

For a person trying to read in a hurry, a font or typestyle that the author may consider to be routine, such as script, can be a major distraction; therefore, don't use script, italics, or any other unusual or hard-to-read typefaces. Remember, you have decided to write for the benefit of the intended user. Forget about your personal preferences and use only the most common print fonts. Also, select a type size that is readable at the intended distance. For example, labeling displayed on the screen of a wall-mounted heart monitor must be readable from several feet away. Also, use a consistent format throughout the document. Also, check the format and section titles against information on the contents page. In some cases, such as for in vitro diagnostic products, the arrangement of information in the labeling may be dictated by regulation.

Page numbers should **not** be referenced in instruction or service manuals. It is very easy for the actual page numbers to be changed during the original writing or when the manual is updated. It is much better to refer to paragraph titles or paragraph numbers as they are less likely to change; and, if changed, titles are more noticeable by writers and typists than are page numbers. The use of correct figure numbers is easy--just check them.

Short and to the Point

It is important to use sentence structure that will convey the intended message with a minimum of misinterpretation or need to reread. Tests have been conducted to determine the ability of readers to follow instructions in a sentence based on the number of activities to be performed. The average person's ability to follow instructions decreases rapidly when a sentence contains more than two facts. (Keep in mind your own experiences in

reading instructions.) Therefore, sentences in labeling need to be short and to the point. Avoid long strings of adjectives and be specific. In many cases, a list of activities to be performed is better than burying the facts in long sentences. If it takes lots of words to get to the point, the reader will probably miss the point! Short, choppy sentences or lists are acceptable in instruction manuals and other labeling. You are not trying to entertain readers with beautiful, flowing prose--rather, you want to "shock" them into remembering key facts until they correctly perform the specified instructions. Thus:

- o use short sentences;
- o get to the point; and
- o be specific.

Try to be as specific as possible with your instructions. For example, "ambient" or "room temperature" generally should not be used. Instead specify the desired or necessary range of operating conditions.

Gobbledygook

Another way to be more specific and shorten sentences is to avoid "gobbledygook." The following terms were collected from actual instruction manuals:

ORIGINAL	EQUIVALENT
Makes provisions for	*
Serves to	*
At the time of	When
In conjunction with	And
Carried out in	Perform
Comes up to	Reaches
Will also serve as a chance to	May
Due to the fact that	Because
Will be sure that will	Ensure
Available through the use of	*
Care should be used so as not to	Be careful
Be provided for positive determination	
Causes power to be applied to	Switches power to

In most cases, the equivalent term in the list can replace the original term. For the asterisked items, the equivalent is simply a direct statement of what is intended. Of the terms listed, the combination most often used is "makes provision for." Simply eliminating "makes provision for" and "be provided for" from labeling will result in an immediate improvement for readers.

Introduce Each Item

Always introduce each control, indicator, device, or subject before they are discussed in the text. The introductions should be brief and may be very brief. Keep in mind the items will be described in more detail later. Abbreviations and new or uncommon terms must be defined. The introductions and definitions prevent the reader from going into mental shock, breaking their train of thought, and asking: What is this? By then the reader has probably forgotten the last two or three facts read. Also, the reader may wonder about any "cliff-hanging" item when they resume reading. This disturbance may detract the person from fully assimilating the next instructions being read. To avoid distractions and confusion, a writer of labeling should always:

- o introduce each item; and
- o define new or uncommon terms.

With respect to definitions, a writer should never give a new meaning to an existing term. For example, quality assurance personnel of medical device firms can no longer use the word "critical" in their routine technical conversations because "critical" was given a specialized definition in the GMP regulation. To avoid this disservice, coin a special term or code number such as Class C, Code 1, or Level 2.

Accentuate Key Terms

Whenever it is stated in instructions that something must be done, then "must" should be underlined, set in bold type, or otherwise delineated. Likewise, caution and warning statements should be delineated by underlining, boxing, bold type, etc. Refer to any regulations or standards for a specific product and use the recommended or required caution statements. When standard terminology exists, creating new caution statements is not the best way for a writer to be creative.

Select Words Wisely

When large print is needed for reading at a distance or to attract attention, signs, caution labels, screen prompts, and control labels generally must be short in order to fit the available space. This situation places a burden on the writer to select terms that convey the desired message. Consider the following wording from two actual highway signs:

PLANT TRAFFIC	NO FISHING
ENTERING HIGHWAY	OFF BRIDGE

Have you ever been run over by a pachysandra? If you can't fish off the bridge, does that mean you are allowed to fish only on or from the bridge? Better choices for the intended messages are: "Traffic entering highway" or "No fishing from bridge."

Try Labeling

Finally, always have someone not familiar with the product operate it **exactly** according to the draft instructions and screen displays, if any. No coaching--this is the "acid" test--good luck! During the trials, note any significant problems and make appropriate corrections to the instructions, prompts, or other labeling. You may also wish to solicit input from actual users of the product with respect to clarity, reading level, etc. The information received will reflect the problems encountered by persons trying to follow the instructions without any preconceived knowledge of the actual operation of the product.

Approval Policy and Procedure

Before release for use, labeling should be reviewed and approved by product development, service, marketing, quality assurance, and other appropriate managers. Manufacturers need to have a policy/procedure which covers the drafting, review, and approval of labeling. This procedure is usually used with an approval form such as the sample that follows. This form is intended for use by a medium-to-large firm; however, the checklist style can be adapted to a small firm. In the form, the areas of concern are listed under the group that is responsible for that concern. Thus, every department in the firm has input into the acceptability of the labeling.

APPROVAL FORM FOR LABELING, ADVERTISING, LITERATURE, Etc.
Return to Approval Coord. after each signature or after checking any "no" box.

Title _____ Document No. ___ DWG No. ____
Intended use/distribution _____
Project Leader/title _____
Approval Coordinator _____

YES	NO	N/A*	ENGINEERING
[]	[]	[]	Technical specs., installation data, & part numbers are correct.
[]	[]	[]	Procedural information is accurate and complete.
[]	[]	[]	Standards imposed by CSA, UL, IEC, etc. are met.
[]	[]	[]	Illustrations are technically accurate and final.
[]	[]	[]	Equipment protection cautions are included where necessary.
[]	[]	[]	Procedures have been checked on production model of the product.
[]	[]	[]	Changes requested in draft have been made or negotiated.
[]	[]	[]	Procedures are safe and effective.
[]	[]	[]	Final draft has been proofread.

Project Engineer: _____ Date: _____
[] Approved [] Approved with noted changes [] Not approved
Engineering Services Mgr: _____ Date: _____
[] Approved [] Approved with noted changes [] Not approved

YES	NO	N/A	SERVICE
[]	[]	[]	Maint./problem solving information is written for intended user.
[]	[]	[]	Lists part numbers needed to accomplish maintenance and repairs.

Service Manager: _____ Date: _____
[] Approved [] Approved with noted changes [] Not approved

YES	NO	N/A	TRAINING AND EDUCATION
[]	[]	[]	Document is adequate for training purposes.
[]	[]	[]	Content of document agrees with experience of training specialists if experienced with this or similar product.

Training Manager: _____ Date: _____
[] Approved [] Approved with noted changes [] Not approved

YES	NO	N/A	MARKETING
[]	[]	[]	Material is effective and complete for intended use.
[]	[]	[]	Material meets the needs of the international market.
[]	[]	[]	Material is professional and projects the company image.
[]	[]	[]	All claims are substantiated by data on file in the company.

Project Manager: _____ Date: _____
[] Approved [] Approved with noted changes [] Not approved
Director Marketing: _____ Date: _____
[] Approved [] Approved with noted changes [] Not approved

YES	NO	N/A	QUALITY ASSURANCE
[]	[]	[]	All hazardous situations are highlighted with adequate warnings.
[]	[]	[]	All FDA requirements, GMP's are met.

Quality Engineer: _____ Date: _____
[] Approved [] Approved with noted changes [] Not approved

Drawing number _____ is entered here and at upper righthand
corner by the Approval Coordinator _____ Date: _____
N/A=not applicable signature

FDA 86-4208 Medical Device Federal Register Documents (Revised June 1986) (PB 87-115481/AS, $13.95).

FDA 86-4209 An Introduction to Transcutaneous Electrical Nerve Stimulation: TENS (PB 87-107884/AS, $11.95).

FDA 86-4210 A Comprehensive Review of Hemodialysis Equipment and Related Peripheral Support Equipment: Efficacy, Efficiency and Safety (Volumes I and II) (PB 86-245404/AS, $28.95).

FDA 86-4211 Hemodialysis Equipment and Practices in Massachusetts (PB 86-242427/AS, $11.95).

FDA 86-4212 Protocol for the Study of Hemodialysis in Ohio (PB 86-245370/AS, $22.95).

FDA 86-4213 State Participation in Dialysis System Investigation (PB 87-108825/AS, $24.95).

FDA 87-4002 Impact Resistant Lenses: Questions and Answers - June 1972 (FDA 81-4002) (Revised September 1987) (PB 88-123021/AS, $12.95).

FDA 87-4179 Device Good Manufacturing Practices Manual - November 1985 (Revised November 1987) (GPO 017-012-00330-3, $18.00) (PB 88-132139, $38.95).

FDA 87-4188 Need Help With Medical Device Regulations? Contact DSMA (supersedes FDA 84-4188) (pamphlet).

FDA 87-4199 Medical Device Establishment Registration - Information and Instructions - May 1987 (supersedes FDA 85-4199) (PB 88-123666/AS, $12.95).

FDA 87-4214 Premarket Approval (PMA) Manual (October 1986) (GPO 017-012-00329-0, $7.50) (PB 87-154365/AS, $18.95).

FDA 87-4215 Orthopaedic Device Labeling -- Guideposts for Concerned Physicians (January 1987) (flyer).

FDA 87-4217 Proceedings of the First International Conference of Medical Devices Regulatory Authorities (ICMDRA) - June 2-6, 1986 (PB 88-123005/AS, $25.95).

FDA 87-4218 Have a New Medical Device? (brochure).

FDA 87-4219 Medical Devices Standards Activities Report (PB 88-123641/AS, $19.95).

FDA 87-4221 Regulatory Requirements for Devices for the Handicapped (PB 88-123013/AS, $12.95).

FDA 87-4222 An Introduction to Medical Device Regulations (pamphlet).

FDA 87-4223 Classifying Your Medical Devices (brochure).

FDA 87-4224 In Vitro Diagnostic Devices: Guidance for the Preparation of 510(k) Submissions (GPO 017-012-00331-1, $3.50) (PB 88-121801/AS, $14.95).

FDA 88-4160 Import and Export - Regulatory Requirements for Medical Devices (August 1988)(GPO 017-012-00336-2, $2.25) (PB 89-121859/AS, $13.95).

FDA 88-4225 Review and Summary of Hemodialysis System Investigative Reports from California, the District of Columbia, Massachusetts and Ohio (PB 88-121793/AS, $19.95).

FDA 88-4226 Medical Device Reporting Questions and Answers (February 1988) (PB 88-192737/AS, $14.95).

FDA 88-4227 Export of Medical Devices: A Workshop Manual (September 1988) (GPO 017-012-00338-9, $10.00) (PB 89-119663/AS, $28.95).

FDA 88-4228 Import of Medical Devices: A Workshop Manual (September 1988) (GPO 017-012-00337-1, $8.50) (PB 89-119671/AS, $21.95).

FDA 88-4229 Applications of DNA Probes for the Diagnosis of Human Infectious Diseases: An Overview (September 1988) (GPO 017-012-00340-1, $2.00) (PB 89-120497/AS, $15.95).

FDA 89-4158 Premarket Notification: 510(k) - Regulatory Requirements for Medical Devices (November 1988) (GPO 017-012-00342-7, $3.75).

U.S. DEPARTMENT OF
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Food and Drug Administration
Center for Devices and Radiological Health
Rockville, Maryland 20857

Labeling – Regulatory Requirements for Medical Devices

FDA 89-4203

GRZAN