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medical devices

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

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 89-420

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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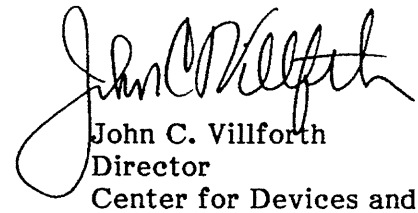
FOREWORD

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.

We welcome your comments and requests for further information.

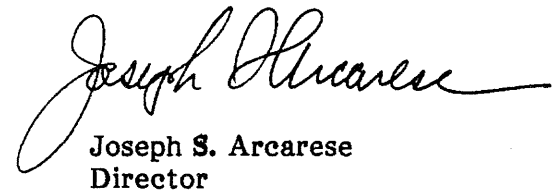


John C. Villforth
Director
Center for Devices and
Radiological Health

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
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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.

CONTENTS

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.;