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 42156, 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
HEALTH AND HUMAN SERVICES

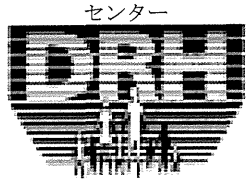
Public Health Service
Food and Drug Administration
Center for Devices and Radiological Health
Rockville, Maryland 20857

FDA 89-4203

本ガイダンスは1997年2月27日にFDAのGood Guidance Practices（GGP：(ガイダンス作成基準)が導入される前に作成された。本ガイダンスは何人に対しても権利を創出または付与するものではなく、FDAまたは国民に対し拘束力を及ぼすものではない。該当する法令または規則、またはこれら両方を満たす代替アプローチがある場合は、その代替アプローチを用いても良い。本ガイダンスは次の改訂版でGGPの標準的要素を含めるよう改訂される予定である。

医療機器

医療機器・放射線保健センター



ラベリング

医療機器に関する規制要件

米国保健福祉省
公衆衛生局
食品医薬品局

医療機器･放射線保健センター(CDRH)刊行物-医療機器

医療機器･放射線保健センター(CDRH)の刊行物は、米国政府印刷局(GPO)または米国技術情報サービス(NTIS)で印刷版の注文が可能であり、注文番号の頭にある GPO または PB によっていずれかを区別できる。また、NTIS からはマイクロフィッシュでも一部 5.95 ドルの価格で入手可能である。「Selected Research in Microfiche」プログラム（で NTIS に口座を作り、「FDA/HFZ」レポートの自動受け取りを依頼することで、全ての CDRH レポートをマイクロフィッシュで一部 1.35 ドルで入手できる。GPO または PB 番号の付いていない刊行物は、CDRH からのみ入手可能である。

注文先住所:Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402; National Technical Information Service, Springfield, VA 22161（北米以外からの注文については、価格はリストに表示されている価格の **2** 倍である）、および Center for Devices and Radiological Health, Food and Drug Administration (HFZ-265), 5600 Fishers Lane, Rockville, MD 20857。価格は変更されることがある。

FDA 84-4190	An Investigation of Cerebrospinal Fluid Shunt Valves - Test Results for Twenty-Five Valves: Final Report - Phase III（脳脊髄液シャントバルブの調査-25 種類のバルブのテスト結果:最終報告書-第Ⅲ相）(PB 84-207042, $22.95)
FDA 84-4191	Medical Device GMP Guidance for FDA Investigators（FDA 調査者のための医療機器 GMP ガイダンス）
FDA 84-4192	Problem Definition Study on Liquid Crystal Forehead Temperature Strips（額用の液晶ストリップ温度計に関する問題定義に関する調査）(PB 84-187483, $16.95)
FDA 85-4169	Toxic Shock and Tampons（中毒性ショックとタンポン）(パンフレット)
FDA 85-4192	Toxic Shock Syndrome（中毒性ショック症候群）（ポスター）
FDA 85-4193	BMD Standards Survey 1982 - International Edition（1982 年医療機器局標準調査-国際版）(PB 85-171155/AS, $34.95)
FDA 85-4194	An Overview of the Medical Device Reporting Regulation（医療機器報告規制の概要）(PB 86-109709/AS, $9.95)
FDA 85-4195	Surface Cracking of Polyurethane Tubing Resulting from Subcutaneous Implantation in Dogs（イヌにおける皮下埋入において発生したポリウレタン製チューブ表面のひび割れ）(PB 85-171619/AS, $11.95)
FDA 85-4196	Medical Device Problem Reporting and the Health Care Professional（医療機器問題の報告と医療専門家）（パンフレット）
FDA 85-4199	Medical Device Establishment Registration: Information and Instructions（医療機器施設の登録：情報と注意事項）(PB 86-123726/AS, $9.95, 8 pp)
FDA 86-4159	Investigational Device Exemptions - Regulatory Requirements for

Medical Devices（研究用医療機器の適用除外－医療機器に関する規制要件（FDA 83-4159 に置き換わる文書）(PB 86-184942/AS, $16.95).

FDA 86-4163 Registration and Listing - Regulatory Requirements for Medical Devices (April 1986)（登録および目録作成－医療機器に関する規制要件［1986 年 4 月］）（FDA 83-4163 に置き換わる文書）(PB 86-191939/AS, $11.95)

FDA 86-4201 Problem Definition Study: Rubella Antibody Testing（問題定義試験：風疹抗体検査）(PB 86-131935/AS, $9.95, 40PP)

FDA 86-4202 To Cement or Not to Cement? or Has the FDA Approved the Use of This Device?（セメントかセメントではないか、あるいは FDA はこの機器の使用を承認しているか）（フライヤー）

FDA 86-4203 Labeling - Regulatory Requirements for Medical Devices（ラベリング—医療機器に関する規制要件）(GPO 017-012-00327-3 $2.75) (PB 86-184348/AS, $11.95)

FDA 86-4204 An Interlaboratory Comparison of Analytical Methods for Ethylene Oxide（エチレンオキシド分析法の検査機関間比較） (PB 86-181856/AS, $9.95)

FDA 86-4205 Accidental Breathing Systems Disconnections (January 1986/Final Report)（呼吸システムの偶発的な接続切断［1986 年 1 月/最終報告書］）(PB 86-185204/AS, $22.95).

（裏表紙の内側に続く）

保健福祉省刊行物　FDA 89-4203

ラベリング

医療機器に関する規制要件

作成：
研修・支援部
小規模製造者支援部門

プロジェクト担当者
Thomas Cardamone

1989 年 8 月

（本刊行物は FDA 86-4203 に置き換わるものである）

米国保健福祉省
公衆衛生局
食品医薬品局
医療機器・放射線保健センター
メリーランド州ロックヴィル 20857

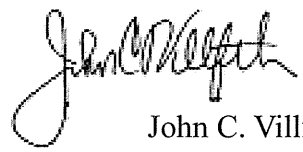
前書き

1982 年 10 月、食品医薬品局は医療機器局および放射線保健局を統合して、医療機器・放射線保健センター(CDRH)を設立した。

CDRH は医療機器および放射線保健の分野において国民の健康を守るための全国プログラムを開発し、実施する部門である。これらのプログラムは医療機器の安全性、有効性、および適切なラベリングの担保、有害な可能性のある電離放射線および非電離放射線に対する人の不要な曝露の制御、およびこのような放射線の安全かつ有効な利用を担保することを目的としている。

CDRH は研究結果を学術誌に発表し、また CDRH の技術報告書として出版している。これらの報告書は、CDRH および契約機関のプロジェクトの結果を広める働きを果たすものである。CDRH の報告書は政府印刷局および米国技術情報サービスで販売されている。

我々は皆様のコメントおよびさらなる情報のリクエストを歓迎する。

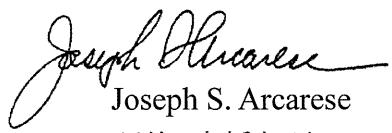


John C. Villforth
医療機器・放射線保健センター所長

序文

本文書は医療機器のラベルおよびラベリングに関する規制および要件を解説する文書である。食品医薬品局は医療機器が安全かつ有効に使用されることを確実とするために、食品・医薬品・化粧品(FD&C)法第 502 条の不正表示に関する規定など（これに限定されない)、多くのラベリング関連の要件を定めている。本文書では、ラベリングとしての広告の問題、誤りのあるラベリングおよび誤解を招くラベリングとは何か、ラベリングの情報はどの程度目立たなければならないか、容器および外側のラベルにどのような情報を表示する必要があるか、使用指示書、処方を要する医療機器の要件、および特定の医療機器または特定種類の医療機器および使用に関する特別なラベリングなどのトピックを説明している。

FD&C 法の医療機器修正法は、「食品・医薬品・化粧品法の要件の遵守の支援を目的として医療機器の小規模製造者に技術支援およびその他の経済的支援以外の支援を与えるための特定可能な部門」の設立を義務付けた。小規模製造者支援部門(DSMA)はこれらの要件を満たす目的で設立されたものである。個別のガイダンスおよびワークショップの提供に加え、DSMA は規則、政策に関する記述、Q&A 小冊子などの多様な印刷物、および製造者が FDA 要件の内容と影響、およびこれらの要件を満たすための最も簡単で有効は方法を理解できるようにするためのその他の FDA 文書を配布している。本文書には、ラベリングの要件を企業が直ちに遵守するための方法の説明と例を示している。我々は本文書の情報によって、FDA のラベリング要件に対する製造者の注意が喚起され、生じ得るあらゆる疑問について製造者が FDA に質問してくれるように期待する。気軽に DSMA を訪問するか、手紙を書くか、またはフリーダイアル 800-638-2041 まで、是非、連絡されたい。電話番号は(301)443-6597 である



Joseph S. Arcarese
研修・支援部長