Guidance on Medical Device Patient Labeling; Final Guidance for Industry and FDA Reviewers

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Labeling Research and Policy Development Branch
Division of Device User Programs and Systems Analysis
Office of Health and Industry Programs

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Preface

Public Comment

Comments and suggestions may be submitted at any time for Agency consideration to Dockets Management Branch, Division of Management Systems and Policy, Office of Human Resources and Management Services, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD, 20852. When submitting comments, please refer to the exact title of this guidance document. Comments may not be acted upon by the Agency until the document is next revised or updated.

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Additional Copies

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Guidance on Medical Device Patient Labeling

This document is intended to provide guidance. It represents the Agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind the Food and Drug Administration (FDA) or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

Introduction:

What is the purpose of this guidance?

This guidance serves a dual purpose:

(1) to assist manufacturers in their development, and

(2) to assist Center reviewers in their review and evaluation

of medical device patient labeling to help make it understandable to and usable by patients (or family members or other lay persons caring for patients).

The writing style we have adopted in this guidance is targeted to manufacturers, since they will be developing the medical device patient labeling.

When translating the professional label into lay language, take care to ensure that it does not alter the intent of the indications, contraindications, warnings and precautions, or other parts of the professional labeling. The lay translation should also provide a balanced presentation of adverse events and the risks and benefits of the device. It should not introduce new claims that are not in the professional label. Device labeling evolves throughout the review process. Therefore, it is your responsibility to ensure that the patient label is consistent with the final professional label.

What is medical device patient labeling?

Medical device patient labeling is any information associated with a device targeted to the patient or lay caregiver. It is intended to help assure that the device is used safely and effectively. This labeling may pertain to therapeutic, restorative, diagnostic, or cosmetic devices.

Medical device patient labeling is supplied in many formats, for example, as patient brochures, patient leaflets, user manuals, and videotapes. This labeling is intended to be supplied, or given to and used by patients or their lay caregivers with or without accompanying professional counseling. Medical device patient labeling may accompany devices intended solely for physicians to operate, devices for both physicians and patients or lay caregivers to operate, and devices operated solely by patients or their lay caregivers.

Why is medical device patient labeling important?

Medical device patient labeling is essential to assure safe and effective use of many, but not all, devices. It informs patients or their lay caregivers about proper use, risks, and benefits of the device in language they can understand.

Medical device patient labeling assists patients or their lay caregivers in understanding the device; its operation, care, and maintenance; the way it interacts with the body to accomplish its purpose; its place and purpose in the patient care regimen; and any safety or disposal issues.

Patient labeling is important for all devices operated by lay users. Adequate directions for operating the devices are needed to make devices safe and effective. For example, as more patients use complex medical devices at home, medical device patient labeling becomes necessary to better communicate to the lay person how to operate the device.

What are the general types of information that may be included in medical device patient labeling?

There are two general categories of information that may be included in medical device patient labeling:

(1) risk/benefit information; and

(2) instructions for use.

Risk/benefit information is information people need to decide to use a device or have it used on them. This information also allows the users to become aware of potential problems with the device. It might include, as appropriate to the device:

- sufficient descriptive information to tell what the device is and what it is used for,
- types of people and situations for whom the device would not be a good choice,
- risks and benefits to the patient or environment associated with the uses of the device,
- information about maintaining the device or identifying potential problems with the device,

- alternative therapeutic and diagnostic choices available, and/or
- other information to enable the person to make an informed decision about the device.

Devices that would have patient labeling consisting primarily or completely of risk/benefit information might be: implants that have no external patient interface once they are implanted, or prescription diagnostic or therapeutic devices that the patient is actively involved in choosing (e.g., laser eye surgery, lithotripsy, intraocular lenses).

Instructions for Use are the procedural steps to follow in setting up, using, cleaning, troubleshooting, and storing a device. This information constitutes the "how to" for the device.

Devices that might have patient labeling that would include instructions for use would be those the patient or lay caregiver has to set up, operate, clean, etc. They might include such devices as suction equipment, intravenous infusion pumps, physical therapy equipment, or transdermal electrical nerve stimulation (TENS) devices.

There are many types of medical devices for which the medical device patient labeling would have both risk/benefit and instructions for use information.

When should you use medical device patient labeling?

Medical device patient labeling should be supplied whenever it can benefit patients or lay caregivers. Patients or lay caregivers benefit from this labeling by increasing their knowledge about the device. Knowledgeable users are more likely to use the device as you intend.

You should know the informational needs of your target audience in order to determine if patient labeling is necessary. Does your audience need or want specific information? Is there something unique about the device (e.g., diagnostic test) that needs to be explained to the patient? Does your audience already know the information?

The following examples illustrate situations where you should consider developing patient labeling. The situations are grouped into risk/benefit information and instructions for use.

You should consider developing risk/benefit information when patients or lay caregivers need to:

- give personal health information to aid their health care practitioner in deciding to use or not use devices in prevention, treatment, or diagnosis of an illness (e.g., magnetic resonance imaging (MRI));

- select among similar devices or device procedures;

- be involved in deciding whether to have a procedure involving the device; and/or

- understand the effect or influence of the device on the patient or others (e.g., orthopedic rods, screws, and fixation devices; genetic screening).

You should consider developing instructions for use when patients or lay caregivers need to:

- maintain the device;
- monitor and report on the operation or output of the device (e.g., pacemakers, glucose monitors);
- explain the operation of the device to others, such as a practitioner caring for another condition of the patient;
- explain the patient's medical situation to others, such as when lay caregivers or others need to understand the requirements of care or the alterations of lifestyle associated with care in the use of the device;
- know how to alter their lifestyles or care regimens to properly integrate the use of the device; and/or
- know how to safely dispose of the device.

You should consider developing both risk/benefit information and instructions for use when patients or lay caregivers need to:

- operate, interpret, and manipulate the device (e.g., programmable implants, home pregnancy test kits, ostomy supplies);
- know how to be careful in using the device, such as understanding the basis for warnings, precautions, and contraindications; and/or
- cooperate with the prevention, treatment, or diagnosis of an illness (e.g., preparation for bone density scan, drugs of abuse test kits).

When is medical device patient labeling not usually necessary?

Medical device patient labeling is not usually necessary when:

- a patient will have no opportunity to benefit from the labeling. The following are typical situations.
    - The device is a tool of the health care practitioner and the patient is not involved in the choice of the device.
    - The device is a tool of the health care practitioner and the patient has no control over or access to the device.
    - The patient can contribute no useful information, such as sensitivities or aversions to materials or abilities to cope with sequelae of device use, that would help the health care practitioner choose or use the device.

        Examples of these types of devices include blood pumps, scalpels, or other surgical instruments.

- a patient's opportunity to benefit from patient labeling is outweighed by the risk of allowing him the opportunity in an emergency. The following is a typical situation.

    - Time is of the essence so that involving the patient, family member, or lay caregiver to help decide on whether to use the device or select among several devices or procedures using devices would be more risky to the patient's health than not involving him. In this case, the health care practitioner subordinates the patient's right to know, choose, and decide to his obligation to give prudent care.

        Examples include devices and device procedures whose need arises unexpectedly and intraoperatively. The patient has no opportunity to read patient labeling before the procedure, such as in the case of some catheters or drains.

What should you consider when identifying a method to distribute the medical device patient labeling?

To increase the likelihood that the patient labeling will reach the patient and be read by the patient or caregiver, consider:

- When should the patient labeling be provided?
- Must an intermediary, such as a health professional or a supplier, pass along the patient labeling or can it be provided directly to the patient?
- If an intermediary is involved, will there by any logistical difficulties in passing the patient labeling along and can these be overcome?

- What are the obstacles to the patient labeling reaching the patient, and what are the solutions to these obstacles?

If you have a Web site, consider placing patient labeling there to help patients get the most up-to-date information.

During pretesting with your target audience, you can ask what method of distribution the audience would prefer and assess experience they have had in the past with the distribution of patient labeling. (See Appendix F Pretesting.)

Suggested Content of Medical Device Patient Labeling:

Determining Sequence and Content:

We are suggesting the sequence and content of the following headings for patient labeling. We have drawn much of this information from FDA's Draft Report on Medical Device Labeling: Patients' and Lay Caregivers" Medical Device Information and Labeling Needs, Results of Qualitative Research." (See References – Sequence.)

Medical device patient labeling should flow logically in brief, simple, clear language with highlighting to guide the user to the desired information to meet the need at the moment. The content should be sequenced in a way that is logical for the intended user, with the most important information presented first. Notice that similar information in this suggested sequence is grouped (chunked) together, an organizational technique that participants in FDA's medical device patient labeling focus groups said they liked. (See References – Sequence.)

A "one size fits all" approach does not work with patient labeling, so the content, and in some cases the sequence, may vary depending on the target audience and the purpose of the medical device patient labeling. Not all of the following headings apply to all medical device labeling. For example, medical device patient labeling presenting only risk/benefit information might not contain headings related to instructions for use.

Through pretesting, such as focus groups, you can systematically gather target audience reactions to your specific medical device patient labeling's content, sequence, and format. Also, you may find in your pretesting that different wording for the suggested headings is appropriate. (See Appendix F Pretesting.)

Table of Contents:

Include a table of contents if the medical device patient labeling is lengthy and/or complex. This helps readers quickly and easily find the information they need.

Glossary:

If a glossary is used, place it after the table of contents to alert readers that it is there to help them. Whether or not a glossary is used, definitions should appear in the text.

Descriptive Information:

Purpose of the device (indications for use):

Briefly describe the FDA cleared or approved indications for use.

Description of the device:

Give a brief physical description of the device, its parts and accessories. A graphic may be the simplest and clearest way to describe a device. All parts of the device shown in the graphic, such as switches, dials, and meters, should be labeled with numbers, letters, or words. The function or purpose of each labeled item should be briefly described in the text of this section. Also, list materials in the device so patients with hypersensitivities can easily identify their risks.

When the device should not be used (contraindications):

Tell when a device should **not** be used (contraindications). Contraindications are conditions under which the device should not be used because the risk of use clearly outweighs any possible benefit. There may be persons in whom the device should not be used because of their health status. For example, the device may be contraindicated for pregnant women.

List known and reasonably foreseeable hazards, not theoretical possibilities. For example, if hypersensitivity to a material in the device has not been demonstrated, it should not be a contraindication. However, if hypersensitivity to a material has not been sufficiently studied and/or is not scientifically documented, clearly state that information.

Contraindications to the use of a device could include:

- demonstrated hypersensitivity to a material where there is patient contact with the device,
- substantial risk of being harmed because of patient characteristics (e.g., age, sex, accompanying therapy, disease state, health status), or
- continued use in the face of an unacceptably hazardous adverse event.

Risks and benefits:

To make an informed choice about a medical device, a patient must have a thorough understanding of the effects and expectations associated with that device. We characterize this as "risk/benefit" information because the decision making process typically involves the weighing of the positive and negative effects and expectations. It is a global concept that may include a number of specific types of information, depending on the device and the target audience.

The goal of risk/benefit information as applied to medical device patient labeling is to provide the patient with information about the risks and benefits associated with a device or procedure in a manner that is meaningful to the user. Risks and benefits conveyed in an effective and meaningful way to the user should aid the user in deciding whether to use a device, or undergo a procedure that uses a device, and to motivate the user to use the device as labeled.

General guidance for developing risk/benefit information:

- Anticipate and respond to people's concerns about their personal risk, or any risks to the environment or society from the use or disposal of the device.
- Carefully word messages that may arouse fear and anxiety.
- Tell patients what they can do specifically to avoid risks.
- Describe risks and benefits clearly and specifically.
- State both benefit and risk information in the same way (e.g., qualitative or quantitative), if possible.
- Be positive in the risk messages. For example, state what the patient can do to overcome risk.
  (E.g., "In rare cases a sweat rash can develop in the contact area. If a sweat rash develops, take the silicone sheet off for a few days, then start again….")
- Balance risk and benefit information. Present factual risk and benefit information without any attempt to influence the patient.
- Pretest risk messages to indicate how effective they are. (See Appendix F Pretesting.)
- Use graphs and other visual materials to communicate risk information. Visuals should be colorful enough to attract attention and simple enough to be understandable at a glance. Combining visuals with brief text that contains the "take-home" message can help to ensure more accurate interpretation of risk information.
- Inform and educate people about risks by using risk comparisons that compare risks that are similar or closely related.

The content of risk messages:

Risk messages should closely reflect the perspective, technical capacity, and concerns of the target audience. The message should:

- include specific actions that people can take, even if it is only to tell them where to go to get further information or assistance.
- avoid using vague or unfamiliar terms to characterize the risk (e.g., "some women," "fourfold," "lifetime risk"). Word choice greatly influences how people attend to risk information (e.g., "risk" raises alarm, "chance" minimizes alarm).
- respect the audience by addressing people's values, preferences, and concerns (e.g., Tell patients about a change in their appearance, such as scarring.),
- seek strictly to inform, not influence.
- assume the audience has little technical knowledge when in doubt about the audience.
- show empathy – with statements that illustrate caring.
- provide facts - two to three bits of supporting data.
- use vivid, concrete images, examples, and anecdotes that communicate on a personal level and make technical risk data come alive.
- limit the comparisons to risks that are similar or closely related when making comparisons.
- caution against unwarranted conclusions.
- provide information on consequences of decisions in a balanced manner.

Risk messages:

- should provide a source for more information.
- should acknowledge uncertainties, including lack of currently available scientific knowledge.
- should include analogies.
- may discuss the nature of the risk.
- may include alternatives.
- may discuss benefits.

The content of benefit messages:

- Present balanced benefit information.
    - Identify outcomes.
    - Estimate the magnitude of outcomes in a way that is meaningful for readers to understand.
    - Evaluate the benefit for individuals.

Evaluation of the effectiveness of the risk/benefit information:

It is important to evaluate the effectiveness of the risk/benefit information by testing it. (See Appendix F Pretesting.)

- Is there adequate *awareness* of the risks and benefits, and their potential consequences?
- Is there *knowledge* of the risks and benefits, and what steps can be taken to lessen the risks?
- What are the *attitudes* toward the risks and benefits?
- What is the *behavior* toward the risks and benefits?

Expectations of the device and the procedure associated with the device:

Tell the patient what to expect before, during, and after a surgical procedure and/or the use of the device. If appropriate, give instructions on post-operative or post-procedural care. If the device is one that the patient operates, and the medical device patient labeling has an "Operating Information" section, the information on what to expect could be included in that section.

General warnings and precautions:

Note: **Please read the detailed discussion in Appendix E of definitions, purpose, content, format, placement, and other issues related to warnings and precautions.**

Embedded in the concept of risk/benefit information is the type of information known as "**general warnings and precautions**." This is the specific hazard alert information that a user needs to know before using the device. Provide this information early in the labeling. Present it according to the clinical significance of the item to assist the reader in understanding the relative importance of the information. By the time readers get to the information on warnings and precautions in the labeling, they have probably already made the decision to use the device. At this point, the users know the global risks and benefits, but need specific information to avoid or reduce a particular hazard associated with the use or disposal of the device. It may be appropriate to include general warnings and precautions in a presentation of risk/benefit information for a device where that information might have bearing on the decision to use the device as well as on the actual safe use, operation, or disposal of the device.

Warnings and precautions tell the reader about hazards, other than those that are contraindications to device use. Warnings and precautions provide information on how to avoid these hazards, i.e., sources of harm in the use of the device.

Importance of the need to adhere to a care regimen:

State why it is important to follow the care regimen explained in the medical device patient labeling. This will help to motivate the user to follow the instructions.

Operating Information:

The user needs to know what to do, how to do it, and when to do it. The operating instructions should:

- focus on **how to** operate the device. It is usually not necessary to provide a detailed explanation for lay users of the mechanism of action of the device or why it does what it does. That approach can lead to information overload.
- assume that the user does not have device or medical knowledge or ability.
- provide logically ordered steps for the task and make the user aware of the importance of doing the steps in order.
- state the purpose and the expected outcome of each task.
- tell the user what steps are essential and which ones are optional.
- be written at an eighth-grade reading level or below to reach most of the population.
- be clear the first time they are read. Many people do not reread something they do not understand.

Setup instructions:

Give clear setup instructions. If a user is not responsible for the setup of the device, tell the user this and omit the setup instructions.

Include in setup instructions for the lay user:

- a parts list, if appropriate.
- list of materials and tools needed for setup.
- unpacking instructions, if appropriate.
- instructions on proper disposal of packing materials or how to return packaging to you for reuse.
- directions for where the device should be placed, such as a table top or floor. Also state if the device should remain in one place after setup.
- any warnings or safety instructions specifically related to setup, placed right before the corresponding task or instruction.
- results of incorrect setup.
- numbered setup instruction steps in logical order.

- any special preparation required before first use of the device, such as cleaning or disinfecting.
- space to write in user-specific instructions.
- who to call if there is a problem. You may refer users to the assistance section in the medical device patient labeling.

Checkout procedures:

If the device requires any type of checkout procedure for safety and effectiveness, clearly and completely explain this process. This task may be as simple as a visual inspection of the device. Other examples of checkout procedures are calibration and quality control checks.

Include:

- when the checkout should be done, such as at the time of setup and/or before each use.
- step-by-step procedures for checking proper function of necessary parts of the device.
- what to do if the checkout shows that the device is not working properly.
- who to call if there is a problem. You may refer users to the assistance section in the medical device patient labeling.

A clock or calendar graphic may be useful to show the user correct times or days to check the device.

Operating instructions:

Give clear and easy-to-follow operating instructions. These instructions should include:

- special preparation the user needs before operation, such as handwashing or device warm-up procedures.
- any warnings or safety instructions specifically related to operation, placed immediately before the corresponding task or instruction.
- results of incorrect operation.
- operating steps in logical order, with the expected results.
- space for user-specific instructions.
- who to call if there is a problem. You may refer users to the assistance section in the medical device patient labeling.

Importance of the need to monitor the activity of the device:

State the importance of monitoring the activity of the device. This section explains that the user needs to make sure the device is acting the way it should. Give examples of what to check to

make sure the device still works properly. For example, check to see that leads are connected, wires are not damaged, and the power is supplied to the device.

Cleaning instructions:

Give clear and complete cleaning instructions.

- List the supplies needed.
- Give step-by-step procedures.
- State how often to clean the device.
- Tell the user what cleaning accomplishes.
- Tell the user what the results of failure to clean will be.
- Include appropriate warnings and precautions for cleaning agents.
- Describe the results of using improper cleaning solutions or methods.
- Include suggestions for the proper disposal of the suggested cleaning agents, if appropriate.

Description of maintenance and who should do it:

- Clearly describe what maintenance actions are the responsibility of the user.
- If a particular kind of user, such as the lay user at home, is not responsible for maintenance, briefly outline proper maintenance actions, who is responsible, and how often the action should be done. The lay user will then know what to expect and can take action if proper maintenance is not provided.
- If the device has some maintenance procedures to be done by the user and some done by others, such as the biomedical engineer, you may wish to write this section in two parts. The two parts will help make clear to users what they should and should not be doing to maintain the device.

Storage instructions:

Clearly describe proper preparation for storage and storage conditions. State the results of improper storage conditions. If extended storage may affect the device, inform the user. It may be necessary to include information that addresses extended storage in the sections on setup, checkout, operation, and maintenance.

Expected failure time and mode and its effect on the patient:

State how long the device will last. State what to expect when the device fails. Let the user know if it fails safely or dangerously and the effect on the patient. Include this type of information in the Risks and Benefits section of the medical device patient labeling if appropriate.

Instructions on how to safely dispose of the device:

When appropriate, explain how to safely dispose of the device (e.g., mercury containing devices, sharps). Include your take-back information, recycling options, and refurbishment options.

Instructions on accessories:

If the device comes with or is used with accessories, discuss all appropriate content areas for each accessory. You could have a separate accessories section or include information on the accessories in the content areas that apply.

You may need to include a general warning at the beginning of the medical device patient labeling advising users of problems that may occur if they use accessories other than those you recommend.

Instructions on related, additional devices:

If the patient will receive an additional device after an operation or procedure, include information about the additional device in the medical device patient labeling. Describe why this additional device would be needed, what symptoms might be expected post-treatment, and any other information about the additional device that impacts the safe and effective use of the primary device. A typical situation is when a patient who has had a home infusion pump with a peripheral line also receives a central line.

Troubleshooting Information:

Troubleshooting:

Provide an easy-to-find troubleshooting section. When a problem occurs, troubleshooting helps determine if the problem is with the device or with the patient's condition. Anticipate any problems the user may have with setup, operation, or maintenance. Provide solutions for these problems in the troubleshooting section. Group similar problems, such as problems with alarms, and highlight each group heading. Highlighting makes it easy to find each group of problems and the specific problems in it. Put the most life-threatening problems first in each section.

Format this section so that the user can locate specific problems quickly. The troubleshooting section could be a table with a column for signs of trouble and a column for actions.

Clearly describe the symptom of each problem in as few words as possible so that the user can easily match the description to the problem observed. If your device displays error messages, list them and what they mean. Explain the steps necessary to correct the problem. Do not confuse the reader with technical reasons for problems unless the reasons are important to the corrective action.

If there are problems that users cannot or should not try to solve themselves, include warnings or precautions and tell them how to get help.

Instruct users to call their health care professionals for emergency assistance if troubleshooting reveals a patient health problem rather than a device problem.

> ***Note:*** Putting assistance information in this section does not eliminate the need for a separate assistance section. (User assistance information is discussed in a later section.)

Tell the user how to report undesirable outcomes (adverse events). For example, the user would report malfunctioning of the device, mistakes in using the device, or injury from the use of the device.

Additional Information:

There are certain categories of information that not all patients want in medical device patient labeling. We refer to these categories as "additional information." Additional information includes such categories as clinical studies and adverse events. Whether or not to include a particular category depends on the needs of the target audience of the particular medical device. You may want to include additional information in appendices in the medical device patient

labeling, or advise the reader that it is available on demand. For example, tell the reader to call the user assistance toll-free telephone number, contact the physician, or go to an Internet site.

FDA's medical device patient labeling focus testing has shown that some patients like all the additional information, but most prefer to see it at the end of the document or have it available on demand so they can choose to read it or not. (See References – Additional Information.)

Clinical studies:

When developing clinical study information for patients, whether as part of the patient labeling to accompany the device, or as an "on demand" piece, make sure it is written in simple, plain language.

Disease and self-care information:

Members of some target audiences may benefit from disease and self-care information. For example, a patient undergoing bone densitometry benefits from information about osteoporosis.

Adverse events:

When appropriate, provide information about any adverse events. Devices whose applications are supported by clinical trials will have data about adverse events that occurred during these trials and that may be of value to the device user. Other devices may have adverse event data from other sources, e.g., published literature or experience with similar devices. The detail in and the need to include an Adverse Events section depend on the benefit of these data to the device user. For a device cleared under Premarket Notification, which was not supported by clinical studies, the Adverse Events section might include only potential adverse events and a statement of the source of the information.

Include potentially fatal adverse events in the Warnings and Precautions section, or the Contraindications section.

If appropriate, follow the listing of adverse events with statements directing the reader to other sections of the labeling for additional information regarding these adverse events and any steps to take to avoid them.

Warranty:

When appropriate, provide any warranty information. Also, for devices intended to be implanted in the human body for more than one year, consider providing a card or sticker listing

the manufacturer of the implant, date implanted, model number, lot number, size, type, or any other appropriate descriptive information. Patients can keep this as part of their personal medical records.

Travel or international use:

If a patient could travel with the device, provide appropriate travel instructions. For example, tell the patient if the medical device is not compatible with foreign power systems. The patient will need an adapter, and may need a converter to convert to the proper voltage. Also, tell the patient to check with the carrier to confirm that the device can be carried and/or used on the airplane.

Index:

Provide an index if the medical device patient labeling is lengthy and/or, complex. This helps readers quickly and easily find the information they need.

Date of Printing:

Put the date that the medical device patient labeling is issued or revised where it can be easily found (e.g., cover or last page). FDA requires dated labeling for prescription devices (21CFR801.109(e)) and recommends it for all other devices.

User Assistance Information:

Design a clearly marked section that advises users on how to get help for problems with the device. FDA's medical device patient labeling focus groups indicated that users look at the end of the medical device patient labeling for the user assistance information, although it can be included in other places in addition to the end. (See References – User Assistance Information.) This section should be very easy for the user to find. It may be as simple as putting the customer assistance number near the company name, device name, and model number. The medical device patient labeling can include a toll-free number or the number for customer assistance, as well as an Internet address.

Provide space near the user assistance information, with appropriate identifying terms, for phone numbers of the medical equipment supplier, the home health care agency, the doctor, the referral for disposal of the device, and/or any other appropriate points of contact for the typical user.

Note: Ideally, your toll-free number should be on the device.

Appendix A

Readability:

Readability defined:

Readability is defined as the ease of understanding or comprehension achieved by the style of writing. Reading involves both decoding and comprehension. The reader must be able to recognize (decode) the words in the medical device patient labeling as well as comprehend the meaning of the text. We encourage you to follow the following guidance to assess and enhance readability.

Assessing readability:

To assess readability, analyze qualitative factors (e.g., explanation of jargon, careful organization) in combination with quantitative factors (results of readability formulas). You should test the medical device patient labeling with a sample of likely, representative users of the device.

A qualitative analysis:

Use these qualities in the text to enhance the reader's comprehension of the medical device patient labeling:

- Define complex medical terminology and jargon when it first appears in the text.
- Carefully organize medical device patient labeling from a user's perspective (organized in the way the user will use the information). Repeat important points and summarize important information, to increase the reader's recall and reading comprehension. The reader will remember the message when key points are reinforced.
- Organize sections with headings and questions.

A quantitative analysis (readability formulas):

The reading level of the medical device patient labeling should be no higher than the eighth-grade level, the average reading level among adults. To predict the reading level of the medical device patient labeling, use the readability formulas (manual or software programs) available. (See References: Readability.)

Readability formulas use semantic (vocabulary difficulty) and syntactic (sentence length) factors to predict the readability of the medical device patient labeling. If the reading level is predicted to be above the eighth-grade level, the patient labeling should be rewritten by applying the

principles of writing for increased comprehension (see Appendix B), and qualitative factors that can enhance reading comprehension. These formulas should be used to predict (not measure) the reading level of the text.

The formulas should not be used to write, rewrite, and revise medical device patient labeling to specific readability levels. While readability formulas can predict readability, the reader must actually read the text to determine if it is readable. To mechanically substitute easier for harder words does not necessarily make the text more readable. Such text could become harder to understand through loss of organization and cohesion and loss of clarity of concepts. As reading expert George Klare explains, merely shortening words and sentences to improve readability is like holding a lighted match under a thermometer when you want to make your house warmer. The thermometer certainly goes up, but the room does not get any warmer.

Testing:

Test the medical device patient labeling with a sample of appropriate users of the device. This is the only way to know if the medical device patient labeling is understandable and useful. User-oriented testing helps to find places where the medical device patient labeling may be inaccurate, incomprehensible, or poorly organized. Since reading is an interactive process between the reader and the text, testing the medical device patient labeling with the target audience is the best way to determine how well the audience understands the labeling.

A summary of readability:

Use qualitative factors in concert with readability formulas to assess the readability of medical device patient labeling. Reader background knowledge and interest, context clues (words that surround a particular word or passage and can throw light on its meaning), text organization, and opportunity for reinforcement are just a few factors other than formula-derived readability that should be used to predict the readability of medical device patient labeling. The best solution is to pretest the medical device patient labeling with the target audience to see if they comprehend it.

Appendix B

Writing for increased comprehension:

The following principles foster the readable writing of medical device patient labeling. We encourage you to follow these principles in order to write for increased comprehension.

General principles:

Write with a specific type of person in mind.

Stress the "need to know" information.

Use concrete examples to clarify abstract ideas.

Consider who will be using the device:

- Are they elderly, disabled, or children?
- Would their vision or hearing likely be impaired?

Consider where the devices will likely be used.

Group (chunk) similar information together.

Use well-mapped, carefully organized writing. Well-organized material provides occasional repetition and thoughtful summary.

Repeat the most important points to increase patient recall and comprehension.

Emphasize and summarize main points.

Use headings and summaries to aid organization and provide message repetition.

Organize medical device patient labeling to meet varied skill and knowledge needs.

- One approach is to provide one well-segmented, highlighted document with a table of contents and the most-desired, basic information up front. Put additional information in appendices to the primary document, or make it available on demand.

- Another approach is to distribute a quick reference card of important reminder information for the experienced user, in addition to the full patient labeling. Also, the experienced user can benefit from an intermediate form (a mini manual) with an expansion of the important

information in the quick reference card, especially key use information, in addition to the full patient labeling.

Locating information in lengthy and/or, complex medical device patient labeling:

Include a summary page with critical information.

Include a table of contents.

Include an index.

Include page numbers to make it easier to locate information.

Include chapter names and numbers, if chapters are used.

Principles for clear, concise writing:

Eliminate unnecessary words:

- Avoid “aware of the fact that.”

Example

Poor: Be aware of the fact that dampness may affect the device and cause rust.

Better: Dampness may affect the device and cause rust.

- Avoid the unnecessary use of make, made, and making.

Example

Poor: Make an attempt to clean your braces twice a day.

Better: Clean your braces twice a day.

- Substitute a single word for a phrase.

Example

Poor: It may take a good deal of practice to operate the device.

Better: It may take much practice to operate the device.

- Use clear and simple phrases whenever possible.

Example

Poor: Endeavor to ascertain the hospital closest to your home.

Better: Try to find the hospital closest to your home.

- Avoid overuse of “it is.”

Example

Poor: It is possible that you may need to use more cleaner.

Better: You may need to use more cleaner.

- Reduce long, complicated phrases.

Example

Poor: You are not able to use another manufacturer’s cable.

Better: You cannot use another manufacturer’s cable.

- Simplify prepositional phrases.

Example

Poor: Store the device in a dry area at all times.

Better: Always store the device in a dry area.

Technical vocabulary:

- Define technical words or use them in context to help increase comprehension. Use lay language first with the technical word in parentheses. In addition to parentheses, use italics or other highlighting techniques to give the reader a signal for the technical vocabulary.

  Example

  Poor: 65 mm is the tolerance level.

  Better: Do not set this gauge above 65 mm (*tolerance level*).

- Define terms the first time they occur in the text. Keep the definitions simple and concise. If you need to define many words on one page, define them in a set off section of the page on which the words first appear. For example, use a sidebar.

- Provide examples to explain technical words.

- Provide a glossary of technical words. If a glossary is used, it should be placed after the table of contents to alert readers that it is there to help them. Whether or not a glossary is used, definitions should appear in the text.

Word choice:

- Personalize the material by using the second person "you" instead of the third person "he," "she," or "they." Using "you" focuses the information directly to the patient, which makes it more important and personal.

  Example

  Poor: The user should not operate this device near water.

  Better: You should not operate this device near water.

- Use terms consistently throughout the text. Use the same term to identify the device and its parts throughout the medical device patient labeling. Avoid synonyms or alternate phrases.

Example

If you start with “dial,” do not call it a “knob” later.

- Put adjectives and adverbs close to the words they modify.

Example

Poor: Use the wire that is covered with green plastic.

Better: Use the green wire.

- Avoid adverbs that are difficult to define or interpret.

Example

Poor: Respond quickly.

Better: Respond within one minute.

- Use active rather than passive verbs.

Example

Poor: The dial should be turned clockwise.

Better: Turn the dial clockwise.

- Use action verbs, not nouns created from verbs.

Example

Poor: Avoidance of cellular phones is necessary when operating the device.

Better: Avoid cellular phones when operating the device.

- Use specific terms. Vague terms may be misinterpreted.

Example

Poor: Device operates poorly in a cool room.

Better: Device will not operate below 60 degrees F.

- Avoid abbreviations or acronyms. If abbreviations or acronyms are necessary, define them the first time. Use them consistently.

Example

Abbreviation: oxygen instead of O_2

Acronym: home medical equipment
instead of HME

Sentences:

- The burden for short-term memory is greater for longer sentences. Use as few words as possible to present an idea or describe an action.

Example

Poor: Find the opaque plastic container that has a blue line on the upper half of it and fill it with any type of water until you reach the blue line.

Better: Fill the plastic container to the blue line with tap water.

- Use no more than one clause in a sentence.

Example

Poor: Check the power cord and do not use it if you find cuts or frays or it is loosely connected to the device.

Better: 1. Look at the power cord for cuts or frays.
If it is cut or frayed, do not use the device.
2. Tug lightly on the power cord. If it slips out of the device, do not use the device.
3. Call 1-800-xxx-xxxx if you need help.

- Place phrases that describe or explain at the end of the sentence. Phrases at the beginning or in the middle of a sentence may be confusing.

Example

Poor: Before using this device, you should read the instruction manual.

Better: Read the instruction manual before using this device.

- Write the way you talk. Avoid formal language.

Example

Poor: Insert the blue cable into the blue socket on the anterior section of the machine to form a completed circuit of the electrical system.

Better: Plug the blue cord into the blue hole on the front of the machine.

- Express ideas of similar content in similar form.

Example

Poor: Twist the large dial clockwise until it stops. Turning the small dial, move it 3 notches counterclockwise.

Better: 1. Turn the large dial marked X clockwise until it stops.
2. Turn the small dial marked Y counterclockwise 3 notches from the "Off" position.

- Users should be able to read instructions aloud. Do not use parentheses for information that should be read. Parentheses cause the reader to hesitate, making it hard to read. Use parentheses only for extra information such as technical terms.

- Don't promote the product in the medical device patient labeling. Ads or promotions in the text will interfere with the patient's ability to follow instructions.

- Use bullets, lists, or more than one sentence instead of a long sentence that requires a lot of punctuation.

Paragraphs:

- Begin paragraphs with a simple topic sentence that states the main idea.

- Paragraphs should be cohesive about a single thought.

Motivation:

- Focus on what the target audience should **do** as well as **know**. (For example, "If mercury leaks, call the local authorities for help with the mercury spill. Mercury is toxic.")

- Use questions throughout the text as headings and summary points to encourage active learning.

Writing procedures:

- Write procedures in short, identifiable steps. Put the steps in the order they should be performed.

- Before each set of steps, tell the reader how many steps are in the procedure. This helps the reader avoid missing steps.

- Number each step in Arabic numbers such as 1, 2, 3. Do not use Roman numerals such as I, II, III; letters such as A, B, C; or words such as one, two, three. People most readily identify Arabic numbers with steps in a sequence.

- Limit each step to no more than three logically connected actions. If actions are not related, put them in separate steps.

- Make the instructions for each action clear and definite to prevent misunderstandings. This approach is especially critical for steps that require more than one action.

Example

Poor: Turn the machine on.

Better: To turn the machine on:
1. Plug the power cord into an AC outlet.
2. Face the front of the machine. Find the black power switch on the right side.
3. Turn the power switch to the "ON" position.

- Tell the user what to expect from an action.

Example

Poor: Flip the switch to the "ON" position.

Better: Face the front of the machine. Flip the black switch on the left side, marked "ON/OFF," to the "ON" position.
The green light will go on.

- Discuss common errors at the point in the procedures where they are likely to occur. Provide information to prevent and correct use errors.

- Each step should be contained on one page. If the entire step will not fit on a single page, break the step into smaller substeps, each fitting on a page or less. Put more than one step on a page only if each step and accompanying graphics are complete on that page.

- Avoid referring the user to another place in the manual for other information (cross referencing). It is confusing to the reader and interrupts the flow of the procedures. If cross referencing is absolutely necessary, make sure the reader knows when to return to the original place.

Example

Poor: If the alarm sounds, go back to the beginning of chapter X.

Better: If the alarm sounds:

1. Turn to page X.
2. Repeat steps 1 and 2 on page X.
3. Return to step 1 on page Y.

Appendix C

Appearance of text:

What principles should be applied to the physical features of the text?

The speed by which letters and words can be recognized (legibility) can be enhanced by applying the following principles.

Sections:

Divide the text appropriately into short sections. Use headings or other highlighting/separation devices. Major headings, including captions and subtitles, should capture the main points. Within the text, bullet text is helpful.

When creating headings, it is acceptable to use uppercase letters and bold print.

Type:

Base the type size and font on the needs of the target audience.

Use at least a 12 point type size whenever possible. For elderly or visually impaired users, use at least 14 points. For headings, use ranges from 18-36 points.

Use a serif font for the text. It allows more variation among letters than sans serif. This makes the letters easier to recognize.

Use both upper and lower case letters in the body of the text. It is more difficult to read all capital letters.

Use black type on a white background for best contrast. It is the easiest to read.

Paper:

Avoid glossy paper. It may cause a glare.

Use paper heavy enough to prevent text and graphics from showing through.

Highlighting:

Use highlighting techniques to emphasize important words, thoughts, or phrases. Highlighting techniques include bolding, underlining, italics, capital letters, color, background patterns, and white space.

Do not overdo highlighting. It will decrease the impact of the message.

Be consistent in the highlighting methods used.

White space:

Use white space carefully to keep the medical device patient labeling from looking too cramped or too spread out. White space between blocks of text aids the ease of reading.

Justify the left-hand margin. Use ragged right margins.

Use at least $1/16^{th}$ of an inch of white space between lines of text.

Increase the amount of white space around important individual words, text and graphics for emphasis.

Formatting and organizing instructions:

Organize instructions with text, flowchart, or list formats as appropriate.

Use tables to present information graphically to simplify complex information.

- It should complement and supplement the text.
- It should condense statistical information.

Note: In instruction manuals, tables are normally not appropriate and their use should be minimized. If a table is necessary to simplify complex information, include instructions on its use. Label each table clearly.

Use lists when the use of the device requires checking off steps that are completed.

Number steps that must be completed in order.

Bullet lists that have no specific order of importance.

Appendix D

Appearance of graphics:

What principles should be applied to the graphics of the medical device patient labeling?

Photographs and line art attract and keep a reader's interest and are often remembered longer than words. Properly chosen and placed illustrations make the text more meaningful and reduce the burden of details in the text. Use the following principles in the graphics of the medical device patient labeling.

Graphics should:

- attract attention,
- re-emphasize the text of the medical device patient labeling,
- be simple and clearly drawn, without clutter, unneeded background, or extraneous detail,
- demonstrate one concept, single idea, or point of information at a time,
- be placed next to corresponding text,
- use cues such as circles or arrows to point out key information,
- be clearly labeled,
- be easy to understand,
- improve understanding of essential information,
- be recognizable to the audience, and
- fit the target audience.

Set off text and graphic that go together by the use of lines, white space, or titles. If a graphic is referred to in the text, it should have a title, for example, Figure 1.

Use accurate and precise graphics.

- When comparing two illustrations, show the difference. If the difference is not distinct, the reader may get confused.
- Represent only simple concepts in your graphics, either of actions or of the device and its surroundings.
- Confine action graphics to a single action whenever possible.
- Use a separate graphic for each distinct idea.

Graphics should be large enough to see the focal point and important words clearly. Use as few words as possible. Captions should tell readers what to look for in the illustration. Eliminate

detail that is not necessary. The clearest graphics have dark, sharp lines for good contrast. Line drawings and illustrations are clearer than photographs. Photos may have distracting extra images and poor contrast. Simple exploded views or cut-away views may be helpful. Use exploded views only for devices that the user should put together or take apart.

In instruction manuals, tables and graphs are normally not appropriate and their use should be minimized. If a table or graph is necessary, include instructions on its use. Label each table or graph clearly.

Apply the following to symbols and icons.

- A symbol is a sign or picture that has been developed to represent an idea. A symbol should be defined or explained because it doesn't mean anything by itself.

- An icon is a drawing that looks like the idea it is meant to represent. Use icons only with text to explain them.

- Use standardized symbols and icons, or those already understood by the general population. Make sure that your population understands the symbols that you use.

Do not use icons with commonly understood usages to illustrate examples inconsistent with those usages (e.g., a red octagon to indicate "go").

Appendix E

Warnings and precautions:

The purpose of this section is to:

- define and explain the terms ***warnings*** and ***precautions***,
- discuss their use in medical device labeling,
- recommend approaches to effective presentation based on literature and research findings, and
- present some of the common issues associated with warnings and precautions.

Note*: Labeling a device with warnings and precautions is the least preferable method of controlling accidents and injuries. You should make every effort to design the device so that the hazard is eliminated. Only when this is clearly impossible should you resort to a warning or precaution in the labeling. For instance, if the device may be made without toxic substances, this would be the preferred alternative.*

What are warnings and precautions?

Warnings and ***precautions*** are written, pictorial, and/or audible alerts to a hazard. The term used to identify the particular hazard presents the reader with a cue to the seriousness of the hazard.

A warning alerts the reader about a situation which, if not avoided, could result in death or serious injury. [ANSI Z535.4-1998] It may also describe potential serious adverse reactions and safety hazards. The designation of a hazard alert as a "warning" is reserved for the most significant problems. The term **WARNING** is generally used as the signal word for this type of hazard alert. If a problem may lead to death or serious injury, FDA may expect you to highlight the warning by placing it in a box.

The term precaution is used for the statement of a hazard alert that warns the reader of a potentially hazardous situation which, if not avoided, may result in minor or moderate injury to the user or patient or damage to the equipment or other property. [ANSI Z535.4-1998] It may also be used to alert against unsafe practices. This includes the special care necessary for the safe and effective use of the device and the care necessary to avoid damage to a device that may occur as a result of use or misuse. The word **CAUTION** is generally used as the signal word for a precaution statement.

The distinction between warnings and precautions is a matter of degree of likelihood and seriousness of the hazard. The target audience for medical device labeling (health care practitioners and lay users of home use devices) generally recognize a hierarchy of hazard alerts,

with warnings being those of a more serious nature and precautions being of a less serious, but important, nature.

What is the purpose of warnings and precautions in medical device labeling?

The basic purpose of a warning or precaution is twofold:

- to inform users of potential personal and environmental hazards, and
- to persuade them to modify their behavior to avoid injury or device damage.

For a warning or precaution to be effective, readers must:

- perceive the threat to be both severe and relevant to them,
- believe that they can perform the recommended response, and
- believe that response will be effective in avoiding the hazard.

Effective warnings and precautions capture the reader's attention, are understood, are consistent enough with the reader's beliefs and attitudes to be accepted, and are persuasive enough to motivate the reader to comply. They invoke an appropriate level of fear arousal, conveying the nature and extent of the hazard, without being so strong that they backfire, causing the reader to select an alternative action or no action.

What is appropriate content of an effective warning or precaution?

There are four elements generally recognized by the courts and research (See References – Warnings and Precautions) as necessary for an effective warning or precaution:

- **a signal word** (**WARNING**, **CAUTION**) to alert the reader that what follows is important hazard information. A symbol or icon may emphasize the effect of the signal word. Additional enhancement, such as bolding, larger type, underlining, italics, or color may help the information stand out from the rest of the text. However, studies have demonstrated that a large difference in font size between the signal word and the text may de-emphasize the importance of the text and therefore reduce the likelihood that the text will be read.
- **a hazard avoidance directive** in the form: **Do Not, Never, Avoid..."** (or **Do**, if more appropriate) followed by the action to avoid (or perform). The objective of this directive is to give clear instructions to the user on how to avoid the hazard.
- **a clear statement of the nature of the hazard** associated with the warning (e.g., allergic reaction to material, strong magnetic field) or precaution (e.g., environmental effect, damage from resterilization) that characterizes the severity and the likelihood.
- the **consequences**, specifying the serious adverse events, potential safety hazards and limitations in device use that result if users do not follow instructions. The purpose is to

give them a clear idea of the risk, which is likely to increase compliance. Hazard alert research has shown that this element has a significant effect on readers. If the consequences are not included, the alert is likely to be less effective.

The signal word should appear first. The order provided here for the other three elements (hazard avoidance, hazard identification, and consequences) will be appropriate for most instances, but may be altered as necessary to best communicate the information to the reader.

How is an effective warning or precaution formatted?

No magic formula works in every instance. The writer must apply the principles discussed here for writing effective warnings and precautions as appropriate to the user and the device.

We suggest that you present warnings and precautions in "clusters" of issues that provide the reader with the information in the most logical and usable order for the particular device. For instance, a surgical device may have the warnings and precautions grouped, or clustered, into Preoperative Information, Intraoperative Information, and Postoperative Information, with appropriately highlighted headers. A home use device may have warnings and precautions grouped according to Setup, Calibration, Use, Storage, and Disposal. There are many possible groupings of this important hazard avoidance information, including the use of a "Before You Start" subsection for devices deemed to need a select and very limited group of warnings and precautions to be read before the device is handled at all. Within each cluster, we encourage you to prioritize the information by clinical significance. If there are no logical clusters or groupings of the hazard information, arrange warnings and precautions in order of clinical significance.

Warnings and precautions should be as concise and focused as possible while providing sufficient information. We recommend using bullets, rather than full sentences. Each bullet should contain a single item. We recommend against grouping a number of warnings or precautions in paragraph form. Users are more likely to read and comply with warnings or precautions presented in outline form using plenty of white space and consistent indentations, rather than paragraphs.

Additional approaches that can assist readers to notice, understand, and comply with warnings and precautions include:

- Integrating warnings and precautions into the task/hazard-related context. This increases the chance that the reader will encounter the information when he is most receptive to it.
- Using concrete rather than abstract terms and jargon. Frank language makes the writing more interesting and therefore more likely to be remembered. For example, say "Contact with this product will produce severe burns" rather than "Contact with this product will result in serious injury."
- Using the simplest possible construction.

- Making each warning and precaution conspicuous. The use of white space and simple highlighting techniques can call attention to the warning or precaution. Do not bury this important information in extensive text.
- Standardizing terms and formatting across the labeling and, if possible, across products to increase consumer recognition.

Where should warnings and precautions be placed for maximum effect?

Research shows that hazard alerts are most effective when integrated into the task information at the most relevant location. Medical device labeling has traditionally contained separate sections for warnings and precautions. This approach predates much of the research into hazard alert effectiveness. However, there is a reluctance to abandon the placement of this important information in separate sections in medical device labeling because of user familiarity with this format. Some research has shown that short, well-highlighted warning messages can actually get users to read a set of longer, more detailed warnings in another section of the labeling. We recommend that warnings and precautions included in the separate sections be those that can be taken out of procedural context and still be effective.

Procedurally related warnings and precautions that cannot be taken out of context should be located with the associated procedural step. Research differs on the most effective location relative to relevant text, but placement immediately before the associated procedural task has been shown to be effective. We suggest considering this approach for warnings and precautions that are included in procedural instructions.

What other issues should be considered in designing warnings and precautions?

Because it is difficult to get readers to notice and read warnings and precautions, it is important to know what works with the target audience of the particular device. This is most effectively done by testing draft warnings and precautions on a sample of the target audience. Recommended testing points are when the labeling is being designed and again after it has been implemented. The latter testing can provide information to be used at the next labeling change.

Including too many warnings and precautions, over-warning, dilutes the strength of all of the hazard alerts. We recommend that writers use care in what is designated as a warning or precaution. Careless designation can have the same diluting effect as over-warning (e.g. "WARNING! Batteries not included."). Repeated exposure to unnecessary hazard alerts (not relevant or already known) reduces the effectiveness of the important warnings and precautions.

We know that readability indexes can predict, but do not measure the reader's actual ability to comprehend labeling. Because of the complexity of the process by which individuals interact

with hazard alerts, you should not rely on readability indexes to predict warning and precaution comprehension.

Appendix F

Pretesting:

What is pretesting?

Pretesting of medical device patient labeling is the systematic and formal gathering of target audience reactions to medical device patient labeling's content and format, before the medical device patient labeling is issued in final form. It is typically one of the evaluations conducted in the early stages of message development. Pretesting may assist you in:

- determining which of a number of labeling presentations is most effective for the intended audience and in identifying strengths and weaknesses in the presentation,
- identifying sensitive and controversial elements,
- revising and improving materials before distribution to users, and
- identifying the best method to distribute the labeling to the target audience.

What methods of pretesting the medical device patient labeling should be used?

Pretesting methods include methods such as individual in-depth interviews, focus group interviews, self-administered questionnaires, usability testing, and readability testing (See Appendix A Readability).

Pretesting can check the potential users' comprehension of the medical device patient labeling and their ability to follow instructions in the medical device patient labeling in order to operate the device. User-oriented testing helps to find places where the patient labeling may be inaccurate, incomprehensible, or poorly organized.

Individual in-depth interviews:

A potential user provides ideas and impressions of possible ways that the medical device patient labeling could be most effectively written.

Focus group interviews:

A small group of potential users, usually 8 to 10 people, discusses their perceptions, opinions, beliefs, and attitudes (POBAs) toward the medical device patient labeling. The discussion is guided by a skilled moderator.

Self-administered questionnaires:

Potential users are asked to review the medical device patient labeling, complete the written questions in the questionnaire about the medical device patient labeling, and return it within a specified time.

Usability testing:

The concept of *usability* refers to the extent to which people who use a product can use it quickly and easily to accomplish specific tasks. The usability of a product is composed of the combined usability of the product's sub-components, which can include hardware, software, menus, icons, messages, labels, manuals, reference materials, and software-based help. Consideration of the usability of a device may focus on all or some of these sub-components. For medical devices, patient labeling is often an important sub-component of usability considerations.

Usability testing is a technique designed to determine how usable a product is. This technique involves systematic observation of actual users trying out a product (or sub-component) and the collection of information from the users about aspects of the product that are easy and those that are difficult for them. Performing usability testing on medical device patient labeling materials involves the use of the device and its labeling materials by a group of intended users of the device. Data are then collected on how well the labeling materials support the users, how effectively they are able to use the device, how many and what kind of errors they make, and any difficulties they encounter.

From the perspective of medical device patient labeling reviews, it is desirable for you to demonstrate that labeling materials can be used safely and effectively through the application of *usability testing*. If usability test results are submitted, they can be used to assist the process of reviewing patient labeling. To the extent that safety concerns are adequately reflected in the test, these results can be considered an indication of the adequacy of the medical device patient labeling.

Checklist Summary:

Use this checklist to make sure that you have considered all the recommendations in this guidance.

The medical device patient labeling contains the following content:

- ❑ **Table of Contents**
- ❑ **Glossary**

Descriptive Information:

- ❑ Purpose of the device (indications for use)
- ❑ Description of the device
- ❑ When the device should not be used (contraindications)
- ❑ Risks and benefits
- ❑ Expectations of the device and the procedure associated with the device
- ❑ General warnings and precautions
- ❑ Importance of the need to adhere to a care regimen

Operating Information:

- ❑ Setup instructions
- ❑ Checkout procedures
- ❑ Operating instructions
- ❑ Importance of the need to monitor the activity of the device
- ❑ Cleaning instructions
- ❑ Description of maintenance and who should do it
- ❑ Storage instructions
- ❑ Expected failure time and mode and its effect on the patient
- ❑ Instructions on how to safely dispose of the device
- ❑ Instructions on accessories
- ❑ Instructions on related, additional devices

Troubleshooting Information:

- ❑ Troubleshooting

Additional Information:

- ❑ Clinical studies
- ❑ Disease and self-care information
- ❑ Adverse events
- ❑ Warranty
- ❑ Travel or international use
- ❑ **Index**
- ❑ **Date of Printing**
- ❑ **User Assistance Information**

The medical device patient labeling adheres to the guidance recommended for:

- Readability
- Writing for increased comprehension
- Appearance of text
- Appearance of graphics
- Warnings and precautions
- Pretesting

GRZAN

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