**Device Labeling Guidance #G91-1 (blue book memo) (Text Only)**

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This guidance was written prior to the February 27, 1997 implementation of FDA's Good Guidance Practices, GGP's. It does not create or confer rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both. This guidance will be updated in the next revision to include the standard elements of GGP's.

**General Program Memorandum #G91-1**

Date: March 8, 1991

From: Director, Office of Device Evaluation (HFZ-400)

Subject: Device Labeling Guidance

To: ODE Review Staff

Purpose

The primary purpose of this memorandum is to formalize guidance to ODE

reviewers concerning their review of labeling in device marketing

submissionsr especially premarket approval applications (PhAs). This

guidance is intended to ensure the adequacy of, and consistency in,

device labeling information. The guidance is also intended for industry

use in preparing device labeling.

Background

General labeling requirements for medical devices have been established

in 21 CFR Part 801. Detailed and specific labeling requirements for in

vitro diagnostic products were promulgated under 21 CFR 809.10. Neither

of these, however, provide specific definitions or explanations of some

significant terms such as warnings, precautions, contraindications and

adverse reactions. The lack of definitions for such terms leads to

misunderstandings and disagreements between PMA applicants and the ODE

review staff. Because labeling content is a key factor in the CDRH

determination of whether there is reasonable assurance that a device is

safe and effective for its intended user such disputes have unnecessarily

prolonged PMA review times.

Scope and Application of the Guidance

Portions of the attached "Device Labeling Guidance" that are based upon

definitions and requirements in the act and applicable regulations

include appropriate references thereto. Guidance on "Indications for

Use," "Contraindications," "Warnings," "Precautions" and "Adverse

Reactions" paraphrase applicable provisions in the labeling requirements

for prescription drugs (21 CFR Part 201). Consistency between drug and

device labeling content and the terminology therein will help minimize

misunderstandings by medical practitioners and patients.

While this guidance is primarily intended to ensure the adequacy of, and

the consistency in, the labeling information for devices subject to

premarket approval, it may also contribute to premarket notification

reviews. As indicated in the "Blue Book" 510(k) Memorandum #86-3 dated

June 30, 1986, a premarket notification must normally only contain

proposed labeling sufficient to describe the device's intended use.

Accordingly, the Sl0(k) decision letter finding a device to be

substantially equivalent advises that this finding does not connote

approval of the proposed labeling. Nevertheless, in the case of in vitro

diagnostic devices, devices with special labeling requirements under

Subpart H of 21 CFR Part 801, and devices for which the inclusion of

specific directions for use, contraindications, warnings, etc. in the

labeling may be critical to a finding of equivalence, the ODE premarket

notification labeling review includes an evaluation of the compliance of

the proposed labeling, or portions thereof, with applicable requirements

under 21 CFR Parts 801 and 809, as appropriate.

This guidance was prepared by Charles H. Kyper, Assistant to the

Director, Office of Device Evaluation, with input from the CDRH Office of

Compliance and Surveillance, Office of Health Affairs, and Office of

Training and Assistance.

It should be understood that the attached guidance is not a regulation

and that, as such, variations can occur and should be given appropriate

consideration. Based upon the preceding discussion, the need for and

usefulness of this guidance should be apparent. ODE reviewers are

encouraged to refer to this guidance during labeling reviews and to

provide it in correspondence and meetings with representatives of the

device industry when appropriate. Reviewers should also keep in mind

that this guidance is not intended to limit the consideration of factors

that may be specific to the device when reviewing its labeling.

Effective Date: This memorandum is effective immediately.

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Attachment

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 DEVICE LABELING GUIDANCE

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 I. Definitions

 Label: A "label" is a display of written, printed or

 graphic matter upon the immediate container of

 any article.[section 201(k).]

 Labeling: "Labeling" includes all labels and other

 written, printed or graphic matter (1) upon

 any article or any of its containers or

 wrappers, or (2) accompanying such article.

 [section 201(m).]

 Intended Uses: The term "intended uses" refers to the

 objective intent of the persons legally

 responsible for the labeling of the device.

 The intent is determined by their expressions

 or may be shown by the circumstances

 surrounding the distribution of the device.

 This objective intent may, for example, be

 shown by labeling claims, advertising matter,

 or oral or written statements by such

 representatives. It may be shown by the

 offering or the using of the device, with the

 knowledge of such persons or their

 representatives, for a purpose for which it is

 neither labeled nor advertised. (21 CFR

 801.4)

 Directions for Use: The term "Directions for use" provides

 directions under which the practitioner or

 layman (e.g., patient or unlicensed health

 care provider), as appropriate, can use

 the device safely and for the purposes for

 which it is intended. Directions for use

 also include indications for use and

 appropriate contraindications, warnings,

 precautions and adverse reaction

 information. Directions for use

 requirements applicable to prescription

 and over-the-counter devices appear

 throughout 21 CFR Part 801 and, in the

 case of in vitro diagnostic products,

 under 21 CFR 809.10.

 II. Safety and Effectiveness Considerations (21 CFR 860.7)

 In determining the safety and effectiveness of a device for

 its intended use, the following factors are to be considered

 and addressed in the device's labeling by the inclusion of

 appropriate information:

 The persons for whose use the device is represented or intended

 - The conditions of use for the device, including conditions of

 use prescribed, recommended or suggested in the labeling or

 advertising of the device, and other intended conditions of use;

 The probable benefit to health from the use of the device

 weighed against any probable injury or illness from such use;

 The reliability of the device; and,

 Other relevant factors.

 III. Indications for Use

 General Statement of Indications for Use

 The general statement of the "Indications for Use" identifies the

 target population in a significant portion of which sufficient

 valid scientific evidence has demonstrated that the device as

 labeled will provide clinically significant results and at the same

 time does not present an unreasonable risk of illness or injury

 associated with the use of the device. As appropriate, the

 labeling should state that the device (trade name) is "indicated"

 or "intended for use"

 (1) in the treatment, mitigation, prevention or diagnosis of a

 recognized disease or condition or an important

 manifestation of a disease or condition; and/or,

 (2) in the relief or mitigation of symptoms associated with a

 disease or condition; and/or,

 (3) as an aid or adjunct to a mode of therapy or diagnosis.

 Additional Information

 When indicated or intended for use in selected subgroups of a

 population with a disease, symptom, or syndrome, the labeling

 should

 (1) describe the available evidence and state the

 limitations of usefulness of the device;

 (2) identify specific tests needed for the selection or

 monitoring of the patients;

 (3) if available, provide information on the

 approximate kind, degree and duration of improvement

 to be anticipated; and

 (4) if relevant, include information regarding the

 recommended intervals between device use, the usual

 duration of treatment, or any modifications of such.

 When safety considerations are such that the device should be

 reserved or restricted for use in certain situations

 (e.g., cases not responsive to other devices, surgical

 procedures or drugs), this information shall be stated.

 When there are specific conditions that should be met before the

 device is used on a long-term basis (e.g., demonstration of

 responsiveness to the device in a short term trial), the

 labeling should identify the conditions or, if the indications

 for long-term use are different from those for short-term use,

 the labeling shall identify the specific indications for each

 use.

 When there is a common belief that the device may be effective

 for a certain use or there is a common use of the device for a

 condition but the preponderance of evidence related to the use

 or condition demonstrates that the device is ineffective, FDA

 may require that the labeling state that there is a lack of

 evidence that the device is effective for that use or condition.

 IV. Contraindications

 This section describes situations in which the device should not

 be used because the risk of use clearly outweights any possible

 benefit. Examples that may, but not always, contraindicate the

 use of a device include:

 Hypersensitivity to an ingredient of a permanently

 implanted device;

 Substantial risk of being harmed because of age, sex,

 concomitant therapy, disease state or other condition; or,

 Continued use in the face of an unacceptably hazardous

 adverse reaction.

 Known hazards and not theoretical possibilities are to be

 listed, e.g., if hypersensitivity to an ingredient in the device

 has not been demonstrated, it should not be listed as a

 contraindication. The "Contraindications" section shall

 immediately follow the "Indications for Use" section of the

 labeling. If no contraindications are known, this section of

 the labeling should state "None known."

 V. Warnings

 Describe serious adverse reactions and potential safety hazards,

 limitations in use imposed by them, and steps that should be

 taken if they occur.

 Include an appropriate warning if there is reasonable evidence

 of an association of a serious hazard with the use of the

 device. A causal relationship need not have been proved.

 A warning is appropriate when the device is commonly used for a

 disease or condition for which there is a lack of valid

 scientific evidence of effectiveness for that disease or

 condition and such usage is associated with a serious risk or

 hazard.

 VI. Precautions

 Include information regarding any special care to be exercised

 by the practitioner and/or patient for the safe and effective

 use of the device, for example:

 - Indicate or emphasize any need for protective wear during

 use.

 - Identify any laboratory tests or other evaluations that

 may be helpful in following the patient's response or in

 identifying adverse reactions and, if appropriate,

 specify the frequency of such tests or evaluations

 before, during and after use of the device.

 The "Precautions" section of the labeling includes precautionary

 statements not appropriate for inclusion under other sections of

 the labeling. Additional guidance regarding precautions will be

 found in the "Special Patient Populations" section below.

 VII. Special Patient Populations

 Limitations on the usage of a device may be necessary for

 various reasons including lack of long-term safety and

 effectiveness data, lack of safety and effectiveness data for

 specific patient populations (e.g., pregnant women), growth

 processes still occurring in the body, and anatomical or

 physiological limitations on the effectiveness of the device.

 If the safety and effectiveness of the device for use in

 specific patient populations have not been established on the

 basis of valid scientific evidence, the "Indications for Use"

 section shall specifically identify the persons for whose use

 the device is indicated and the "Precautions" section shall

 include the following statement:

 "Safety and effectiveness in (e.g., pregnant women,

 children under the age of ..., etc.) have not been

 established."

 If use of the device in a certain patient population is

 associated with a specific hazard, the hazard shall be described

 in the "Precautions" section or, if appropriate, the hazard

 shall be stated in the "Warnings" or "Contraindications" section

 and the "Precautions" section of the labeling shall refer to it,

 e.g., "See 'Warnings' section for information on....."

VIII. Adverse Reactions

 An adverse reaction is an undesirable effect, reasonably

 associated with the use of the device, that may occur as part of

 the effect of the device or may be unpredictable in its

 occurrence.

 This section includes all adverse reactions reasonably

 associated with the use of the device, including those mentioned

 in the "Contraindications", "Warnings" and "Precautions"

 sections of the labeling. The listing of the adverse reactions

 should be followed, if appropriate, by statements directing the

 reader to other sections of the labeling for additional

 information regarding these adverse reactions and any steps that

 should be taken.

 Adverse reactions should be listed in descending order according

 to their clinical significance as determined by their severity

 and frequency. Provide frequency data from adequately reported

 clinical studies when the data is not well known to the device

 user (practitioner and/or patient) and/or when needed in

 deciding between the use of the device and an alternative

 procedure or approach.

 IX. Prescription Devices

 A prescription device is, by definition under 21 CFR 801.109, a

 device which, because of any potentiality for harmful effect, or

 the method of its use, or the collateral measures necessary to

 its use, is not safe except under the supervision of a

 practitioner licensed by law to direct the use of the device,

 and hence for which "adequate directions for use" (21 CFR 801.5)

 cannot be prepared.

 A prescription device, other than surgical instruments, is

 misbranded if its label does not bear:

 (1) the statement, "Caution: Federal law restricts this

 device to sale by or on the order of a ",

 the blank to be filled with the word "physician",

 "dentist", or with the descriptive designation of any

 other practitioners licensed by the law of the

 State in which that person practices to use or order

 the use of the device; and

 (2) the method of application or use of the device.

 A prescription device is misbranded if its labeling does not

 bear:

 (1) information for use including indications, effects,

 routes, methods, frequency and duration of

 administration, and any relevant hazards,

 contraindications, side effects, and precautions under

 which practitioners licensed by law to administer the

 device can use the device safely and for the purpose

 for which it is intended, including all purposes for

 which it is advertised or represented, with the

 exceptions that

 (a) such information may be omitted from the

 dispensing package if, but only if, the

 directions, hazards, warnings, and other

 information are commonly known to

 practitioners licensed by law to use the

 device and the FDA Commissioner is requested

 to offer an opinion on a written proposal

 stating reasonable grounds to omit such

 information from the dispensing package;

 (b) such information will not be required on so

 called reminder-piece labeling which calls

 attention to the name of the device but does

 not include indications or other use

 information; and

 (2) the date of the issuance or the latest revision of the

 labeling, except for labels and cartons, that bears

 directions for the use of the device.

 X. Restricted Device

 Under the authority of section 515(d)(1)(B)(ii) of the Federal

 Food, Drug, and Cosmetic Act (the act), the approval order for a

 premarket approval application (PMA) may require, as a condition

 of approval, that the sale, distribution and use of the device

 be restricted but only to the extent permitted under section

 520(e) of the act. Under section 520(e) of the act, FDA may

 require that a device be restricted to sale, distribution and

 use only upon the written or oral authorization of a

 practitioner licensed by law to administer or use such devices

 (i.e., prescription device) or upon such other conditions that

 FDA may prescribe. Such a requirement must be based upon a

 determination by FDA that, because of the device's potentiality

 for harmful effect or the collateral measures necessary to its

 use, there cannot otherwise be reasonable assurance of its

 safety and effectiveness. If the device is restricted to use by

 persons with specific training or experience in its use or by

 persons for use in certain facilities, FDA must determine that

 such a restriction is required for the safe and effective use of

 the device. A person cannot be excluded from using a device,

 however, solely because that person does not have the training

 and experience to make him/her eligible for certification by a

 certifying board recognized by the American Board of Medical

 Specialties or has not been certified by such a Board.

 When the sale, distribution and use of a device are restricted

 in a PMA approval order or by regulation under section 520(e) of

 the act, the label must include appropriate statements of the

 restrictions imposed by FDA (e.g., restrictions on the sale,

 distribution and use of the device or restrictions on the use of

 the device to persons with specific training or experience in

 its use or to persons for use in certain facilities). The

 label shall bear the statement, "Caution: Federal law restricts

 this device to sale, distribution and use by or on the order of

 a ", the blank to be filled with the word

 "physician", "dentist", or with the descriptive designation of

 any other practitioners licensed by the law of the State in

 which that person practices to use or order the use of the

 device and, if applicable, followed by a descriptive phrase of

 the training or experience required (e.g.,"trained and/or

 experienced in ",the blank to be filled with, as

 appropriate, "the use of this device" or specified therapeutic

 or diagnostic procedures) and/or the facilities to which use is

 restricted.

 In accordance with the provisions of section 502(r) of the act,

 advertisements and other descriptive printed material issued by

 the manufacturer, packer or distributor with respect to a

 restricted device must include the following among other

 things:

 (1) a true statement of the device's established name

 (common or usual name unless there is an official name

 designated by FDA or recognized in an official

 compendium), printed prominently and in type at least

 half as large as that for any trade or brand name for

 the device; and

 (2) a brief statement of the intended uses of the device

 and relevant warnings, precautions, side effects, and

 contraindications.

 Except in extraordinary circumstances, FDA cannot require prior

 approval of the content of any advertisement except in the case

 of any printed matter which FDA determines to be labeling as

 defined in section 201(m) of the act.

 XI. Patient Information Labeling

 Patient information labeling includes labeling directed to the

 patient as well as family members and others who administer home

 use devices to patients, e.g., care providers who oversee the

 use of infant apnea monitors and nebulizers. In determining

 whether patient information labeling is appropriate for a

 prescription device, the following factors, among others, should

 be considered:

 - Should the patient be aware of alternative(s) to

 the use of the device if a choice is available?

 Are substantial risks or discomforts associated with

 the use of the device?

 Is the need for strict patient adherence to a specific

 treatment regimen required?

 Does substantial public or professional controversy

 exist about the device and its related procedures?

 Patient information labeling shall include the indications for

 use and relevant contraindications, warnings, precautions and

 adverse reactions using terminology well known and understood by

 the average layman. Technical terms should be kept to a minimum

 and should be defined when necessary. If applicable, directions

 to ensure safe and effective use of the device by the patient

 shall be included. Patient information labeling, if possible,

 should not exceed the seventh grade reading comprehension level.

 The following sources may provide useful information regarding

 the information to be included as well as the terminology to be

 used in patient information labeling:

 1. U.S.P. Dispensing Information, Volume II, Advice for the

 PatientR, Drug information in Lay Language

 2. American Medical Association Drug Evaluations

 XII. Disclaimer of Liability

 Inclusion in the labeling of a disclaimer regarding the safety

 and effectiveness of the device for its indicated or intended

 use is to be avoided. Instead, labeling and promotional

 material may include an objective and accurate representation

 of the clinical experience with the device whereby the

 practitioner and patient are made aware not to expect a

 completely safe and effective outcome with the use of the

 device in all cases.

 Inclusion of disclaimers of liability for any medical expenses

 or any direct or consequential damages resulting from or

 caused by any defect, failure or malfunction of the device

 will not inhibit FDA in imposing the notification and

 otherremedies (repair, replacement or refund) provisions of

 section 518 of the act. The provisions of section 518 may be

 imposed whenever FDA determines that:

 (1) The device presents an unreasonable risk of

 substantial harm to the public health;

 (2) There are reasonable grounds to believe that the

 device was not properly designed and manufactured

 within the state of the art; or

 (3) There are reasonable grounds to believe that the

 unreasonable risk was not caused by failure of a

 person other than the manufacturer, importer,

 distributor or retailer of the device to exercise

 due care in the ... use of the device.

XIII. Misbranding

 Pertinent provisions in the law and implementing regulations

 related to medical device labeling and enforced by FDA appear

 below. It is important that these provisions be kept in mind

 both in the development of labeling by the device industry and

 in the labeling review by CDRH.

 Section 502 of the Federal Food,Drug, and Cosmetic Act (the

 act) provides that a device shall be deemed misbranded if:

 (1) Its labeling is false or misleading in any particular.

 (2) The label does not bear the name and place of business

 of the manufacturer, packer or distributor and an

 accurate statement of the quantity of contents in

 terms of weight, measure or numerical count.

 (3) Any required word, statement or other information to

 appear on the label or labeling is not prominently

 placed thereon with such conspicuousness and in such

 terms as to render it likely to be read and understood

 by the ordinary individual under customary conditions

 of purchase and use.

 (4) Labeling does not bear adequate directions for use and

 such adequate warnings against use in those

 pathological conditions or by children where its use

 may be dangerous to health, or against unsafe dosage

 or methods or duration of administration or

 application in such manner and form as are necessary

 for the protection of users.

 (5) In the case of a restricted device, its advertising is

 false or misleading in any particular.

 (6) In the case of a restricted device, advertisements and

 other descriptive printed matter (other than labeling)

 issued by the manufacturer, packer or distributor do

 not include a brief statement of the intended uses of

 the device and relevant warnings, precautions, side

 effects and contraindications.

 In determining whether a device is misbranded because the

 labeling or advertising is misleading, section 201(n) of the

 act permits the following to be taken into account among other

 things:

 (1) representations made or suggested by statement,

 word, design, device, or any combination thereof; or

 (2) the extent to which the labeling or advertising

 fails to reveal facts material in the light of such

 representations or material with respect to the

 consequences which may result from the use of the

 device to which the labeling or advertising

 relates under the conditions of use prescribed in

 the labeling or advertising or under such conditions

 of use as are customary or usual.

 Regulations applicable to medical devices provide that the

 inclusion of any of the following representations in device

 labeling constitutes misbranding of the device:

 21 CFR 801.6 - False or misleading representation with respect

 to another device or a drug

 21 CFR 807.39 -Any representation that creates an impression

 of official approval because of registration or

 (e.g.,i clusion of FDA establishment

 registration number)

 21 CFR 807.97 - Any representation that creates an impression

 of official approval because of complying with

 the premarket notification regulations

 (e.g., inclusion of premarket notification

 reference number)

 XIV. Prohibited Acts

 Section 301(1) of the act prohibits the use in any labeling or

 advertising for the device of any representation or suggestion

 that approval of an application with respect to the device is

 in effect under section 515 of the act (premarket approval) or

 that the device complies with the provisions of section 515.

https://www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm081368.htm