**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