ラベリング、広告、資料などの承認フォーム

各署名が入れられてから、または「no」ボックスにチェックが入れられてから、承認調整担当者に返却のこと

標題_____文書番号_____図面番号_____

意図される使用／販売_____

プロジェクトリーダー／役職名_____

承認調整担当者_____

YES	NO	N/A*	製造部門
[]	[]	[]	技術仕様、設置データ、および部品番号が正しい
[]	[]	[]	手順に関する情報が正確かつ完全
[]	[]	[]	CSA 規格、UL 規格、IEC 規格が定める基準を満たしている
[]	[]	[]	図が技術的に正確で完全である
[]	[]	[]	必要に応じて、機器の保護に関する注意が含められている
[]	[]	[]	当該製品の製造モデルを用いて手順の点検を実施している
[]	[]	[]	ラベリング案に要求した変更が実施されているか、協議されて処理されている
[]	[]	[]	手順は安全かつ有効である
[]	[]	[]	最終案の校正を終了している

プロジェクトエンジニア：_____日付：_____

[] 承認 [] 指摘した変更により承認 [] 承認しない

製造部門責任者：_____日付：_____

[] 承認 [] 指摘した変更により承認 [] 承認しない

YES	NO	N/A	保守点検
[]	[]	[]	維持管理に関する情報／問題解決のための情報が意図する使用者に対して記述されている
[]	[]	[]	維持管理および修理の実施に必要な部品番号のリストが示されている

保守管理部門責任者：_____日付：_____

[] 承認 [] 指摘した変更により承認 [] 承認しない

YES	NO	N/A	研修および教育
[]	[]	[]	文書は研修目的に適切である
[]	[]	[]	文書の内容は、当該または同様の製品の経験がある場合、研修専門家の経験と一致している

研修部門責任者：_____日付：_____

[] 承認 [] 指摘した変更により承認　　[] 承認しない

YES	NO	N/A	マーケティング部門
[]	[]	[]	資料は意図する使用に対して有効で完全である
[]	[]	[]	資料は国際市場のニーズに適合している
[]	[]	[]	資料は専門的であり、企業イメージを投影するものである
[]	[]	[]	全ての主張は社内ファイルのデータで証明されている

プロジェクトマネージャー：_____日付：_____
[] 承認 [] 指摘した変更により承認　　[] 承認しない
マーケティング部門責任者：_____日付：_____
[] 承認 [] 指摘した変更により承認　　[] 承認しない

YES	NO	N/A	品質保証
[]	[]	[]	全ての危険な状況が強調されて、適切な警告が付けられている
[]	[]	[]	FDA 要件、GMP 要件を全て満たしている

品質エンジニア：_____日付：_____
[] 承認 [] 指摘した変更により承認　　[] 承認しない

承認調整担当者__（署名）_____が図面番号を右欄_____、および右上角の欄に入れる　　日付：_____
*N/A=該当しない

FDA86-4208　Medical Device Federal Register Documents（医療機器に関する連邦官報文書）（1986 年 6 月改訂）（PB 87-115481/AS,$13.95).

FDA 86-4209　An Introduction to Transcutaneous Electrical Nerve Stimulation: TENS（経皮的電気的神経刺激:TENS の概要）（PB 87-107884/AS, $11.95).

FDA 86-4210　A Comprehensive Review of Hemodialysis Equipment and Related Peripheral Support Equipment: Efficacy, Efficiency and Safety（血液透析装置および関連する周辺サポート装置の包括的レビュー:有効性、効率、および安全性）（I 巻および II 巻）（PB 86-245404/AS,$28.95).

FDA86-4211　Hemodialysis Equipment and Practices in Massachusetts（マサチューセッツ州における透析装置と診療）(PB 86-242427/AS,$11.95).

FDA 86-4212　Protocol for the Study ofHemodialysis in Ohio（オハイオ州における血液透析の研究プロトコル）(PB 86-245370/AS, $22.95).

FDA 86-4213　State Participation in Dialysis System Investigation（州の透析システムに関する調査への参加）(PB 87-108825/AS, $24.95).

FDA87-4002　Impact Resistant Lenses: Questions and Answers - June 1972（耐衝撃

レンズ:質問と答え-1972年夏)(FDA 81-4002)(1987年9月改訂)(PB 88-123021/AS, $12.95).

FDA 87-4179 Device Good Manufacturing Practices Manual - November 1985(医療機器のGMPマニュアル-1985年11月)(1987年11月改訂)(GPO 017-012-00330-3, $18.00)(PB 88-132139, $38.95).

FDA87-4188 Need Help With Medical Device Regulations? Contact DSMA(医療機器規則について助けが必要な場合はDSMAに連絡)(FDA 84-4188に置き換わる文書)(パンフレット).

FDA 87-4199 Medical Device Establishment Registration - Information and Instructions - May 1987(医療機器施設登録-情報および指示-1987年5月)(FDA 85-4199に置き換わる文書)(PB 88-123666/AS, $12.95).

FDA87-4214 Premarket Approval (PMA) Manual(市販承認申請(PMA)マニュアル)(1986年10月)(GPO 017-012-00329-0, $7.50)(PB 87-154365/AS, $18.95).

FDA 87-4215 Orthopaedic Device Labeling - Guideposts for Concerned Physicians(眼科用機器のラベリング-関心のある医師に対する指針)(1987年1月)(広告)

FDA 87-4217 Proceedings of the First International Conference of Medical Devices Regulatory Authorities (ICMDRA) - June 2-6, 1986(第1回医療機器規制当局国際会議(ICMDRA)紀要-1986年6月2～6日)(PB 88-123005/AS, $25.95).

FDA 87-4218 Have a New Medical Device?(新しい医療機器がありますか)(パンフレット).

FDA 87-4219 Medical Devices Standards Activities Report(医療機器規格業務報告書(PB 88-123641/AS, $19.95).

FDA87-4221 Regulatory Requirements for Devices for the Handicapped(障害者用の機器の規制要件)(PB 88-123013/AS,$12.95).

FDA 87-4222 An Introduction to Medical Device Regulations(医療機器規則の概論)(パンフレット).

FDA 87-4223 Classifying Your Medical Devices(医療機器の分類)(パンフレット).

FDA 87-4224 In Vitro Diagnostic Devices: Guidance for the Preparation of 510(k) Submissions(体外診断機器:510(k)提出の準備のガイダンス)(GPO017-012-00331-1, $3.50)(PB 88-121801/AS, $14.95).

FDA88-4160 Import and Export - Regulatory Requirements for Medical Devices(輸入および輸出-医療機器の規制要件)(1988年8月)(GPO 017-012-00336-2, $2.25)(PB 89-121859/AS, $13.95).

FDA88-4225 Review and Summary of Hemodialysis System Investigative Reports from California, the District of Columbia, Massachusetts and Ohio(カリフォルニア州、コロンビア特別区、マサチューセッツ州、およびオハイオ州からの血液透析システム調査報告書のレビューおよび要約)(PB 88-121793/AS, $19.95).

FDA88-4226 Medical Device Reporting Questions and Answers(医療機器報告に関

する質問と答え)（1988 年 2 月）（PB 88-192737/AS, $14.95).

FDA 88-4227 Export of Medical Devices: A Workshop Manual（医療機器の輸出:ワークショップマニュアル)（1988 年 9 月）（GPO 017-012-00338-9, $10.00)（PB 89-119663/AS, $28.95).

FDA88-4228 Import of Medical Devices: A Workshop Manual（医療機器の輸入:ワークショップマニュアル)（1988 年 9 月）（GPO 017-012-00337-1, $8.50)（PB 89-119671/AS, $21.95).

FDA88-4229 Applications of DNA Probes for the Diagnosis of Human Infectious Diseases: An Overview（ヒト感染症の診断への DNA プローブの応用:概要)（1988 年 9 月）（GPO 017-012-00340-1, $2.00)（PB 89-120497/AS, $15.95).

FDA89-4158 Premarket Notification: 510（k) - Regulatory Requirements for Medical Devices（市販前届:510（k)-医療機器の規制要件)（1988 年 11 月）（GPO 017-012-00342-7, $3.75)

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

【 米 国 ② 】

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

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 S10(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

Attachment - Page 1

DEVICE LABELING GUIDANCE
Table of Contents

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.

Links on this page:

機器のラベリングに関するガイダンス**#G91-1**（ブルーブック・メモランダム）（本文のみ）
本ガイダンスは1997年2月27日にFDAのGood Guidance Practices（GGP：ガイダンス作成基準）導入される前に作成された。本ガイダンスは何人に対しても権利を創出または付与するものではなく、FDAまたは国民に対し拘束力を及ぼすものではない。該当する法令または規則、またはこれら両者を満たす代替アプローチがある場合は、その代替アプローチを用いても良い。本ガイダンスは次の改訂版でGGPの標準要素を含めるよう改訂される予定である。

一般プログラム・メモランダム**#G91-1**
発行日：1991年3月8日

発行者：機器評価部(ODE)部長(HFZ-400)

標題：機器のラベリングに関するガイダンス

対象：ODE審査担当職員

目的

本メモランダムの主要目的は、ODEの審査担当職員に対し、機器販売承認申請、特に市販前承認申請(PMA)におけるラベリングの審査に関する公式の指針を示すものである。本ガイダンスは機器のラベリングの情報の適切性および一貫性を確かなものとすることを目的としている。さらに、業界における機器のラベリングの準備に使用されることも目的としている。

背景

医療機器に対する一般ラベリング要件は21 CFR Part 801で定められている。体外診断用製品に特異的なラベリング要件は、21 CFR 809.10の下で公布された。しかし、これらはいずれも、警告、使用上の注意、禁忌、および副作用などの複数の重要な語の定義または説明を示していない。このような語の定義が示されていないことは、PMA申請者とODE審査担当職員の間に誤解および意見の相違を生じさせる。ラベリングの内容は、機器が意図する使用者に対して安全かつ有効であることの妥当な証拠が存在するかのCDRHによる判定における主要因子であるため、このような議論はPMAの審査期間を不必要に延長させている。

本ガイダンスの範囲と適用

添付した「機器のラベリングに関するガイダンス」の法律および適用される規則の定義および要件に基づく部分には、それらに対する適切な参照が付けられている。「適応」、「禁忌」、「警告」、「使用上の注意」、および「副作用」に関する指針は、処方薬のラベリング要件(21 CFR Part 201)における該当する規定を言い換えたものである。医薬品および機器間のラベリングの内容およびラベリングに使用する用語の一貫性は、医師および患者の誤解を最小とするために有用であろう。本ガイダンスは主に市販前承認の審査を受ける機器のラベリングに含まれる情報の適切性および一貫性を確実とすることを目的としているが、市販前届の審査にも有用であろう。1986 年 6 月 30 日発行の「ブルーブック(Blue Book)」510(k)メモランダム(Memorandum) #86-3 で示されている通り、市販前届には通常、機器の使用目的を説明するに十分なラベリング案のみを含めなければならない。従って、機器が本質的に同等であるとする 5l0(k) 決定通知は、その決定がラベリング案の承認を意味するものではないと通知している。しかし、体外診断用機器、21 CFR Part 801 の Subpart H の下で特別なラベリング要件が定められている機器、およびラベリングに特別な使用法、禁忌、警告などを含めることが同等性の決定にとって重要となる可能性のある機器の場合には、ODE による市販前届のラベリングの審査に、ラベリング案、またはその一部と 21 CFR Part 801 および 809 の該当する要件との適合性の評価が必要に応じて含められる。

本ガイダンスは医療機器・放射線保健センター(CDRH)のコンプライアンス・調査部(Office of Compliance and Surveillance)、保健業務部(Office of Health Affairs)、および研修・支援部(Office of Training and Assistance)からの情報提供を受けて、ODE 副部長 Charles H. Kyper が作成した。

添付したガイダンスは規則ではなく、そのため差異が生じる可能性があり、適切に考慮されるべきであることを理解されたい。前述の説明に基づき、本ガイダンスの必要性および有用性は明確なはずである。ODE 審査担当者は、ラベリングの審査時に本ガイダンスを参照すること、および機器業者の代表者との連絡および会議の中で本ガイダンスを必要に応じて示すことが推奨される。また、本ガイダンスは機器のラベリングの審査時に機器に特異的である可能性のある因子の考慮を制限しようとするものではないことを、審査者は心に留めておくべきである。

発効日：本メモランダムは即時に有効である。

機器のラベリングに関するガイダンス
目次

I 定義

ラベル：　「ラベル」とは、あらゆる物品の直接の容器の上における文字、印刷、または図案による表示である[section 201(k)]。

ラベリング：　「ラベリング」は、(1) あらゆる物品、あるいはその容器または包装材に表示される、または(2) これらの品物に付随する、全てのラベル、およびその他の文字、印刷、または図案による表示を含む[section 201(m)]。

使用目的：　「使用目的」という語は、機器のラベリングに法的責任を持つ者の客観的な意図である。この意図はこのような人による表現によって決定されるか、機器の販売を取り巻く状況によって示される場合がある。この客観的な意図は、例えば、ラベリングにおける主張、広告物、またはこのような代表者による口頭または文章による陳述によって示される場合がある。これは、このような人またはその代表者の承知の上で、機器を表示または広告以外の目的のために提供または使用することよって示される場合がある(21 CFR 801.4)。

使用法：　「使用法」という語は、臨床家または一般の人（例、患者や免許を受けていない医療提供者）が必要に応じて機器を安全に、意図されている目的のために使用できるような指示を示すものである。さらに、使用法には、適応、および適切な禁忌、警告、使用上の注意、および副作用に関する情報も含まれる。処方が必要な機器およびOTC機器に適用される使用法の要件は、21 CFR Part 801に定められており、体外診断用製品については、21 CFR 809.10に定められている。

II. 安全性および有効性に関する考慮点(21 CFR 860.7)

機器のその用途における安全性および有効性の評価においては、次の要素を考慮し、適切な情報を組入れることで機器のラベリングにおいて言及するものとする。

機器の使用が代表されている、または意図されている人。
- 処方されている使用の条件、または機器のラベリングまたは広告において推奨または示唆されている使用の条件、およびその他の意図される使用の条件。機器の使用から得られる可能性のある健康ベネフィットのこのような使用から生じる可能性のある損傷または障害に対する比較結果。機器の信頼性。および、
その他の関連因子。

III.適応

適応に関する一般的記述

「適応」に関する一般的記述では、標的集団を特定する。この集団については、その相当な割合に対して、機器が表示の通りに臨床的意義のある結果をもたらし、同時に機器の使用に関連する障害または損傷の不当なリスクを示さないことが、十分かつ妥当な科学的エビデンスにより立証されていること。必要に応じて、ラベリングには機器（商品名）が次において「適応」とされている、または「使用が意図されている」ことを記載すべきである。

(1) 認識されている疾患または状態、または疾患または状態の重要な症状の