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# TITLE 21--FOOD AND DRUGS

# 标题21--食品和药品

# CHAPTER I--FOOD AND DRUG ADMINISTR

# 第I章--食品和药品管理局

# ATION DEPARTMENT OF HEALTH AND HUMAN SERVICES

# 卫生与公众服务部

# SUBCHAPTER H - MEDICAL DEVICES

# H分章-医疗器械

# PART 801 LABELING

# 第801部分 标签

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| **Subpart A General Labeling Provisions** | **A 部分 - 一般标签规定** |
| **Sec. 801.1 Medical devices; name and place of business of manufacturer, packer or distributor.** | **801.1 医疗器械；制造商、包装商或分销商的名称和营业地点。** |
| (a) The label of a device in package form shall specify conspicuously the name and place of business of the manufacturer, packer, or distributor. | (a) 包装形式的器械标签应显着标明制造商、包装商或分销商的名称和营业地点。 |
| (b) The requirement for declaration of the name of the manufacturer, packer, or distributor shall be deemed to be satisfied, in the case of a corporation, only by the actual corporate name which may be preceded or followed by the name of the particular division of the corporation. Abbreviations for "Company," "Incorporated," etc., may be used and "The" may be omitted. In the case of an individual, partnership, or association, the name under which the business is conducted shall be used. | (b) 申报制造商、包装商或分销商名称的要求应被视为满足，在公司的情况下，只有实际的公司名称可以在特定名称之 前或之后公司的分工。可以使用“Company”、“Incorporated”等缩写，“The”可以省略。对于个人、合伙企业或协会，应使用开展业务的名称。 |
| (c) Where a device is not manufactured by the person whose name appears on the label, the name shall be qualified by a phrase that reveals the connection such person has with such device; such as, "Manufactured for ___", "Distributed by _____", or any other wording that expresses the facts. | (c) 如果设备不是由标签上出现姓名的人制造的，则该名称应由表明该人与该设备的联系的短语限定；例如，“为___制 造”、“由____分销”或任何其他表达事实的措辞。 |
| (d) The statement of the place of business shall include the street address, city, State, and Zip Code; however, the street address may be omitted if it is shown in a current city directory or telephone directory. The requirement for inclusion of the ZIP Code shall apply only to consumer commodity labels developed or revised after the effective date of this section. In the case of nonconsumer packages, the ZIP Code shall appear on either the label or the labeling (including the invoice). | (d) 营业地点的说明应包括街道地址、城市、州和邮政编码；但是，如果街道地址显示在当前城市目录或电话目录中， 则可以省略它。包含邮政编码的要求仅适用于本节生效日期后制定或修订的消费品标签。对于非消费品包装，邮政编码 应出现在标签或标签（包括发票）上。 |
| (e) If a person manufactures, packs, or distributes a device at a place other than his principal place of business, the label may state the principal place of business in lieu of the actual place where such device was manufactured or packed or is to be distributed, unless such statement would be misleading. | (e) 如果一个人在其主要营业地点以外的地方制造、包装或分销设备，则标签可以说明主要营业地点，以代替制造或包 装该设备的实际地点，或将分发，除非这样的陈述会产生误导。 |
| **Sec. 801.3 Definitions.** | **801.3 定义。** |
| **As used in this part:** | **在本部分中使用：** |
| Automatic identification and data capture (AIDC) means any technology that conveys the unique device identifier or the device identifier of a device in a form that can be entered into an electronic patient record or other computer system via an automated process. | 自动识别和数据采集 (AIDC) 是指以可以通过自动化过程输入电子病历或其他计算机系统的形式传达唯一设备标识符或 设备的设备标识符的任何技术。 |
| Center Director means the Director of the Center for Devices and Radiological Health or the Director of the Center for Biologics Evaluation and Research, depending on which Center has been assigned lead responsibility for the device. | 中心主任是指器械和放射健康中心主任或生物制品评估和研究中心主任，具体取决于哪个中心被指定负责器械。 组合产品 具有本章第 3.2(e) 节中规定的含义。 |
| Combination product has the meaning set forth in § 3.2(e) of this chapter. | 组合产品具有本章第 3.2(e) 节中规定的含义。 |

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| Convenience kit means two or more different medical devices packaged together for the convenience of the user. | 便利包是指为方便用户而将两种或多种不同的医疗器械包装在一起。 |
| Device package means a package that contains a fixed quantity of a particular version or model of a device. | 设备包是指包含固定数量的特定版本或型号的设备的包。 |
| Expiration date means the date by which the label of a device states the device must or should be used. | 失效日期是指设备标签声明该设备必须或应该使用的日期。 |
| FDA, we, or us means the Food and Drug Administration. | FDA、我们 或我们是指食品和药物管理局。 |
| Finished device means any device or accessory to any device that is suitable for use or capable of functioning. | 成品设备是指适合使用或能够运行的任何设备或任何设备的附件。 |
| Global Unique Device Identification Database (GUDID) means the database that serves as a repository of information to facilitate the identification of medical devices through their distribution and use. | 全球唯一设备识别数据库 (GUDID) 是指充当信息存储库的数据库，以促进通过医疗设备的分发和使用来识别医疗设 备。 |
| Human cells, tissues, or cellular or tissue-based product (HCT/P) regulated as a device means an HCT/P as defined in § 1271.3(d) of this chapter that does not meet the criteria in § 1271.10(a) and that is also regulated as a device. | 作为器械监管的人体细胞、组织或基于细胞或组织的产品 (HCT/P) 是指本章 § 1271.3(d) 中定义的不符合 § 1271.10(a) 标准的 HCT/P 和这也作为一种设备进行监管。 |
| Implantable device means a device that is intended to be placed in a surgically or naturally formed cavity of the human body. A device is regarded as an implantable device for the purpose of this part only if it is intended to remain implanted continuously for a period of 30 days or more, unless the Commissioner of Food and Drugs determines otherwise in order to protect human health. | 可植入装置是指旨在放置在人体的外科手术或自然形成的腔内的装置。 就本部分而言，仅当打算连续植入 30 天或更 长时间时， 设备才被视为可植入设备，除非食品和药物专员为保护人类健康另有决定。 |
| Label has the meaning set forth in section 201(k) of the Federal Food, Drug, and Cosmetic Act. | 标签具有《联邦食品、药品和化妆品法》第 201(k) 节中规定的含义。 |
| Labeler means: | 贴标机的意思： |
| (1) Any person who causes a label to be applied to a device with the intent that the device will be commercially distributed without any intended subsequent replacement or modification of the label; and | (1) 任何人将标签贴在器械上，目的是使器械在商业上销售，而无需随后更换或修改标签；和 |
| (2) Any person who causes the label of a device to be replaced or modified with the intent that the device will be commercially distributed without any subsequent replacement or modification of the label, except that the addition of the name of, and contact information for, a person who distributes the device, without making any other changes to the label, is not a modification for the purposes of determining whether a person is a labeler. | (2) 任何人导致更换或修改设备的标签，其目的是将该设备进行商业销售，而无需随后更换或修改标签，但添加的名称 和联系信息除外。 ，分发设备的人，而不对标签进行任何其他更改，不是为了确定一个人是否是贴标签者而进行的修 改。 |
| Lot or batch means one finished device or more that consist of a single type, model, class, size, composition, or software version that are manufactured under essentially the same conditions and that are intended to have uniform characteristics and quality within specified limits. | 批或批次是指由单一类型、型号、类别、尺寸组成或软件版本组成的一个或多个成品设备，这些设备是在基本相同的条件下制造的，并且旨在在规定的范围内具有统一的特性和质量。 |

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| Shipping container means a container used during the shipment or transportation of devices, and whose contents may vary from one shipment to another. | 运输容器是指在设备运输或运输过程中使用的容器，其内容可能因装运而异。 |
| Specification means any requirement with which a device must conform. | 规范是指设备必须符合的任何要求。 |
| Unique device identifier (UDI) means an identifier that adequately identifies a device through its distribution and use by meeting the requirements of § 830.20 of this chapter. A unique device identifier is composed of: | 唯一设备标识符 (UDI) 是指通过满足本章第 830.20 条的要求，通过其分发和使用充分识别设备的标识符。唯一的设 备标识符由以下部分组成： |
| (1) A device identifier - a mandatory, fixed portion of a UDI that identifies the specific version or model of a device and the labeler of that device; and | (1)器械标识符 ——UDI 的强制性、固定部分，用于标识器械的特定版本或型号以及器械的标签；和 |
| (2) A production identifier - a conditional, variable portion of a UDI that identifies one or more of the following when included on the label of the device: | (2)生产标识符 - UDI 的一个有条件的可变部分，当包含在设备标签上时，它标识以下一项或多项： |
| (i) The lot or batch within which a device was manufactured; | (i) 制造设备的批次； |
| (ii) The serial number of a specific device; | (ii) 特定设备的序列号； |
| (iii) The expiration date of a specific device; | (iii) 特定设备的到期日期； |
| (iv) The date a specific device was manufactured; | (iv) 特定设备的制造日期； |
| (v) For an HCT/P regulated as a device, the distinct identification code required by § 1271.290(c) of this chapter. | (v) 对于作为设备监管的 HCT/P，本章第 1271.290(c) 节要求的独特识别码。 |
| Universal product code (UPC) means the product identifier used to identify an item sold at retail in the United States. | 通用产品代码 (UPC) 是指用于识别在美国零售销售的商品的产品标识符。 |
| Version or model means all devices that have specifications, performance, size, and composition, within limits set by the labeler. | 通用产品代码 (UPC) 是指用于识别在美国零售销售的商品的产品标识符。 |
| **Sec. 801.4 Meaning of intended uses.** | **801.4 预期用途的含义。** |
| The words intended uses or words of similar import in §§ 801.5, 801.119, 801.122, and 1100.5 of this chapter refer to the objective intent of the persons legally responsible for the labeling of an article (or their representatives). The intent may be shown by such persons' expressions, the design or composition of the article, or by the circumstances surrounding the distribution of the article. This objective intent may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives. Objective intent may be shown, for example, by circumstances in which the article is, with the knowledge of such persons or their representatives, offered or used for a purpose for which it is neither labeled nor advertised; provided, however, that a firm would not be regarded as intending an unapproved new use for a device approved, cleared, granted marketing | 预期用途的词 或本章 §§ 801.5、801.119、801.122 和 1100.5 中的类似词是指对物品贴标签负有法律责任的人 （或其代表）的客观意图。意图可能通过这些人的表达、物品的设计或组成，或围绕物品的分发的情况来显示。例如， 这种客观意图可以通过标签声明、广告材料或此类人员或其代表的口头或书面陈述来显示。例如，可以通过以下情况表 明客观意图：在这些人或其代表知情的情况下，该物品被提供或用于既没有标签也没有广告的目的；然而，提供 仅基于 该公司知道医疗保健提供者正在为此类用途开处方或使用此类设备，该公司不会被视为打算对已批准、批准、授予上市 许 |

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| authorization, or exempted from premarket notification based solely on that firm's knowledge that such device was being prescribed or used by health care providers for such use. The intended uses of an article may change after it has been introduced into interstate commerce by its manufacturer. If, for example, a packer, distributor, or seller intends an article for different uses than those intended by the person from whom he or she received the article, such packer, distributor, or seller is required to supply adequate labeling in accordance with the new intended uses. | 可或免于上市前通知的设备进行未经批准的新用途. 物品的预期用途在其制造商引入州际贸易后可能会发生变化。例 如，如果包装商、分销商或销售商打算将物品用于与他或她收到物品的人的预期用途不同的用途，则要求该包装商、分 销商或销售商根据新的预期用途。知道医疗保健提供者正在为此类用途开处方或使用此类设备。物品的预期用途在其制 造商引入州际贸易后可能会发生变化。例如，如果包装商、分销商或销售商打算将物品用于与他或她收到物品的人的预 期用途不同的用途，则要求该包装商、分销商或销售商根据新的预期用途。知道医疗保健提供者正在为此类用途开处方 或使用此类设备。物品的预期用途在其制造商引入州际贸易后可能会发生变化。例如，如果包装商、分销商或销售商打 算将物品用于与他或她收到物品的人的预期用途不同的用途，则要求该包装商、分销商或销售商根据新的预期用途。 |
| Link to an amendment published at 82 FR 2217, Jan. 9, 2017. | 2017 年 1 月 9 日发布于 82 FR 2217 的修正案的链接。 |
| This amendment was delayed until Mar. 21, 2017, at 82 FR 9501, Feb. 7, 2017. | 该修正案被推迟到 2017 年 3 月 21 日，即 82 FR 9501，2017 年 2 月 7 日。 |
| This amendment was further delayed until Mar. 19, 2018, at 82 FR 14319, Mar. 20, 2017. | 该修正案被进一步推迟到 2018 年 3 月 19 日，即 82 FR 14319，2017 年 3 月 20 日。 |
| This amendment delayed indefinitely at 83 FR 11639, Mar. 16, 2018. | 该修正案无限期延迟至 83 FR 11639，2018 年 3 月 16 日。 |
| **Sec. 801.5 Medical devices; adequate directions for use.** | **801.5 医疗器械；足够的使用说明。** |
| Adequate directions for use means directions under which the layman can use a device safely and for the purposes for which it is intended. Section 801.4 defines intended use. Directions for use may be inadequate because, among other reasons, of omission, in whole or in part, or incorrect specification of: | 适当的使用 说明是指外行人可以根据其安全使用设备并用于预期目的的说明。第 801.4 节定义了预期用途。 使用说 明可能不充分，除其他原因外，全部或部分遗漏或不正确说明： |
| (a) Statements of all conditions, purposes, or uses for which such device is intended, including conditions, purposes, or uses for which it is prescribed, recommended, or suggested in its oral, written, printed, or graphic advertising, and conditions, purposes, or uses for which the device is commonly used; except that such statements shall not refer to conditions, uses, or purposes for which the device can be safely used only under the supervision of a practitioner licensed by law and for which it is advertised solely to such practitioner. | (a) 声明此类设备的所有条件、目的或用途，包括在口头、书面、印刷或图形广告中规定、推荐或建议的条件、目的或 用途，以及条件、该设备通常用于的目的或用途；除非此类声明不得提及仅在获得法律许可的从业者的监督下才能安全 使用设备的条件、用途或目的，并且仅针对此类从业者进行广告宣传。 |
| (b) Quantity of dose, including usual quantities for each of the uses for which it is intended and usual quantities for persons of different ages and different physical conditions. | (b) 剂量，包括预期的每种用途的常用量和不同年龄和不同身体状况的人的常用量。 |

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| (c) Frequency of administration or application. | (c) 给药或应用的频率。 |
| (d) Duration of administration or application. | (d) 管理或应用的持续时间。 |
| (e) Time of administration or application, in relation to time of meals, time of onset of symptoms, or other time factors. | (e) 给药或应用时间，与用餐时间、症状发作时间或其他时间因素有关。 |
| (f) Route or method of administration or application. | (f) 给药或应用的途径或方法。 |
| (g) Preparation for use, i.e., adjustment of temperature, or other manipulation or process. | (g) 使用准备，即调整温度或其他操作或过程。 |
| **Sec. 801.6 Medical devices; misleading statements.** | **801.6 医疗器械；误导性陈述。** |
| Among representations in the labeling of a device which render such device misbranded is a false or misleading representation with respect to another device or a drug or food or cosmetic. | 在设备标签中导致此类设备贴错标签的表述中，有关于另一设备或药物、食品或化妆品的虚假或误导性表述。 |
| **Sec. 801.15 Medical devices; prominence of required label statements; use of symbols in labeling.** | **801.15 医疗器械；突出要求的标签声明；在标签中使用符号。** |
| (a) A word, statement, or other information required by or under authority of the act to appear on the label may lack that prominence and conspicuousness required by section 502(c) of the act by reason, among other reasons, of: | (a) 该法案要求或授权出现在标签上的词语、声明或其他信息可能缺乏该法案第 502(c) 节所要求的显着性和显着 性，原因包括： |
| (1) The failure of such word, statement, or information to appear on the part or panel of the label which is presented or displayed under customary conditions of purchase; | (1) 此类文字、声明或信息未出现在在通常购买条件下展示或展示的标签部分或面板上； |
| (2) The failure of such word, statement, or information to appear on two or more parts or panels of the label, each of which has sufficient space therefor, and each of which is so designed as to render it likely to be, under customary conditions of purchase, the part or panel displayed; | (2) 此类文字、声明或信息未能出现在标签的两个或多个部分或面板上，每个部分或面板都有足够的空间，并且每个部 分的设计都使其可能会出现在购买的惯常条件，展示的部件或面板； |
| (3) The failure of the label to extend over the area of the container or package available for such extension, so as to provide sufficient label space for the prominent placing of such word, statement, or information; | （三）标签未延伸到容器或包装可延伸的区域，为突出放置该文字、声明或信息提供足够的标签空间； |
| (4) Insufficiency of label space for the prominent placing of such word, statement, or information, resulting from the use of label space for any word, statement, design, or device which is not required by or under authority of the act to appear on the label; | （4）标签空间不足以突出放置此类文字、声明或信息，这是由于将标签空间用于任何文字、声明、设计或设备，而该文 字、声明、设计或设备并非由该行为要求或在该行为授权下出现标签上； |
| (5) Insufficiency of label space for the placing of such word, statement, or information, resulting from the use of label space to give materially greater conspicuousness to any other word, statement, or information, or to any design or device; or | (5) 标签空间不足以放置此类文字、声明或信息，这是由于使用标签空间使任何其他文字、声明或信息或任何设计或装 置更加显眼；或者 |
| (6) Smallness or style of type in which such word, statement, or information appears, insufficient background contrast, obscuring designs or vignettes, or crowding with other written, printed, or | (6) 此类文字、声明或信息出现的字体小或样式、背景对比度不足、设计或插图模糊不清，或与其他书面、印刷或图形 材料挤在一起。 |

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| graphic matter. | |
| (b) No exemption depending on insufficiency of label space, as prescribed in regulations promulgated under section 502(b) of the act, shall apply if such insufficiency is caused by: | (b) 根据该法第 502(b) 条颁布的法规中的规定，如果标签空间不足是由以下原因引起的，则不适用因标签空间不足 而产生的豁免： |
| (1) The use of label space for any word, statement, design, or device which is not required by or under authority of the act to appear on the label; | (1) 将标签空间用于该行为未要求或未经授权出现在标签上的任何文字、声明、设计或装置； |
| (2) The use of label space to give greater conspicuousness to any word, statement, or other information than is required by section 502(c) of the act; or | (2) 使用标签空间使任何词语、陈述或其他信息比该法案第 502(c) 条的要求更显眼；或者 |
| (3) The use of label space for any representation in a foreign language. | (3) 对任何外语表示的标签空间的使用。 |
| (c)(1)(i) All words, statements, and other information required by or under authority of the act to appear on the label or labeling for a device shall appear thereon in one or more of the following formats: | (c)(1)(i) 该法案要求或授权出现在器械标签或标签上的所有文字、声明和其他信息应以下列一种或多种格式出现在其 上： |
| (A) The English language; | (A) 英语； |
| (B) In the case of articles distributed solely in Puerto Rico or in a Territory where the predominant language is one other than English, the predominant language may be substituted for English; | (B) 如果文章仅在波多黎各或主要语言不是英语的领土上分发，则可以用主要语言代替英语； |
| (C) A symbol accompanied by adjacent explanatory English text, or text in the predominant language of the Territory, in the case of articles distributed solely in Puerto Rico or in a Territory where the predominant language is one other than English; | (C) 仅在波多黎各或在主要语言不是英语的领土上发行的文章，带有相邻的英文解释性文字或该领土主要语言的文字的 符号； |
| (D) A symbol not accompanied by adjacent explanatory text that: | (D) 不附有相邻说明文字的符号： |
| (1 ) Is contained in a standard that FDA recognizes under its authority in section 514(c) of the act; | ( 1 ) 包含在 FDA 根据其授权在该法案第 514(c) 节中认可的标准中； |
| (2 ) Is used according to the specifications for use of the symbol set forth in FDA's section 514(c) recognition; and | ( 2 ) 根据 FDA 第 514(c) 条认可中规定的符号使用规范使用；和 |
| (3 ) Is explained in a paper or electronic symbols glossary that is included in the labeling for the device and the labeling on or within the package containing the device bears a prominent and conspicuous statement identifying the location of the symbols glossary that is written in English or, in the case of articles distributed solely in Puerto Rico or in a Territory where the predominant language is one other than English, the predominant language may be used; | ( 3 ) 在包含在器械标签中的纸质或电子符号词汇表中进行了解释，并且包含器械的包装上或内部的标签带有突出和显 眼的声明，以识别用英文书写的符号词汇表的位置或者，如果文章仅在波多黎各或主要语言不是英语的地区分发，则可 以使用主要语言； |
| (E) A symbol not accompanied by adjacent explanatory text that: | (E) 不附有相邻说明文字的符号： |
| (1 ) Is established in a standard developed by a standards development organization (SDO); | ( 1 ) 建立在标准制定组织（SDO）制定的标准中； |
| (2 ) Is not contained in a standard that is recognized by FDA under its authority in section 514(c) of the act or is contained in | ( 2 ) 不包含在 FDA 根据该法案第 514(c) 节的 |

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| a standard that is recognized by FDA but is not used according to the specifications for use of the symbol set forth in FDA's section 514(c) recognition; | 授权认可的标准中，或包含在 FDA 认可但未按照符号使用规范使用 的标准中在 FDA 的第 514(c) 条承认中规定； |
| (3 ) Is determined by the manufacturer to be likely to be read and understood by the ordinary individual under customary conditions of purchase and use in compliance with section 502(c) of the act; | ( 3 ) 由制造商确定为在符合该法案第 502(c) 条的习惯购买和使用条件下可能被普通个人阅读和理解； |
| (4 ) Is used according to the specifications for use of the symbol set forth in the SDO developed standard; and | ( 4 ) 按照 SDO 制定的标准中规定的符号使用规范使用；和 |
| (5 ) Is explained in a paper or electronic symbols glossary that is included in the labeling for the device and the labeling on or within the package containing the device bears a prominent and conspicuous statement identifying the location of the symbols glossary that is written in English or, in the case of articles distributed solely in Puerto Rico or in a Territory where the predominant language is one other than English, the predominant language may be used; | ( 5 ) 在包含在器械标签中的纸质或电子符号词汇表中进行了解释，并且在包含器械的包装上或内部的标签上有一个突 出和显眼的声明，以识别用英文书写的符号词汇表的位置或者，如果文章仅在波多黎各或主要语言不是英语的地区分 发，则可以使用主要语言； |
| (F) The symbol statement "Rx only" or "â?? only" may be used as provided under § 801.109(b)(1). | (F) 符号声明“Rx only”或“â?? only”可以按照 § 801.109(b)(1) 的规定使用。 |
| (ii) The use of symbols in device labeling which do not meet the requirements of paragraph (c)(1)(i) of this section renders a device misbranded under section 502(c) of the act. | (ii) 在器械标签中使用不符合本节 (c)(1)(i) 段要求的符号会导致器械在该法案第 502(c) 条下贴错标签。 |
| (iii) For purposes of paragraph (c)(1)(i) of this section: | (iii) 为本节 (c)(1)(i) 段的目的： |
| (A) An SDO is an organization that is nationally or internationally recognized and that follows a process for standard development that is transparent, (i.e., open to public scrutiny), where the participation is balanced, where an appeals process is included, where the standard is not in conflict with any statute, regulation, or policy under which FDA operates, and where the standard is national or international in scope. | (A) SDO 是一个获得国家或国际认可的组织，遵循透明的标准制定流程（即向 公众监督开放），参与平衡，包括上诉 程序，标准与 FDA 运作所依据的任何法规、法规或政策不冲突，并且该标准在国家或国际范围内。 |
| (B) The term "symbols glossary" means a compiled listing of: | (B) 术语“符号词汇表”是指汇编列表： |
| (1 ) Each SDO-established symbol used in the labeling for the device; | (1) 设备标签中使用的每个 SDO 建立的符号； |
| (2 ) The title and designation number of the SDO-developed standard containing the symbol; | (2) SDO 制定的标准的名称和名称编号，包含该符号； |
| (3 ) The title of the symbol and its reference number, if any, in the standard; and | (3) 标准中的符号名称及其参考编号，如果有的话；和 |
| (4 ) The meaning or explanatory text for the symbol as provided in the FDA recognition or, if FDA has not recognized the standard or portion of the standard in which the symbol is located or the symbol is not used according to the specifications for use of the symbol set forth in FDA's section 514(c) recognition, the explanatory text as provided in the standard. | (4) FDA 认可中提供的符号的含义或解释性文字，或者，如果 FDA 未认可该符号所在的标准或标准的一部分，或者 该符号未根据使用规范使用FDA 第 514(c) 条认可中规定的符号，标准中提供的解释性文本。 |
| (2) If the label contains any representation in a foreign language, | (2) 如果标签包含任何外文表述，则该行为要求 |

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| all words, statements, and other information required by or under authority of the act to appear on the label shall appear thereon in the foreign language. | 或授权出现在标签上的所有文字、陈述和其他信息均应以外文出现。 |
| (3) If the labeling contains any representation in a foreign language, all words, statements, and other information required by or under authority of the act to appear on the label or labeling shall appear on the labeling in the foreign language. | (3) 如果标签包含任何外文表述，则该行为要求或授权出现在标签或标签上的所有文字、声明和其他信息均应以外文出 现在标签上。 |
| **Sec. 801.16 Medical devices; Spanish-language version of certain required statements.** | **801.16 医疗器械；某些必需声明的西班牙语版本。** |
| If devices restricted to prescription use only are labeled solely in Spanish for distribution in the Commonwealth of Puerto Rico where Spanish is the predominant language, such labeling is authorized under § 801.15(c). | 如果仅限于处方使用的设备仅以西班牙语标记，以便在以西班牙语为主要语言的波多黎各联邦分发，则此类标签已根据 § 801.15(c) 获得授权。 |
| **Sec. 801.18 Format of dates provided on a medical device label.** | **801.18 医疗器械标签上提供的日期格式。** |
| (a) In general. Whenever the label of a medical device includes a printed expiration date, date of manufacture, or any other date intended to be brought to the attention of the user of the device, the date must be presented in the following format: The year, using four digits; followed by the month, using two digits; followed by the day, using two digits; each separated by hyphens. For example, January 2, 2014, must be presented as 2014-01-02. | (a) 一般而言。当医疗器械的标签包括印刷的失效日期、制造日期或任何其他旨在引起器械用户注意的日期时，日期必 须以下列格式显示：年份，使用四个数字; 后跟月份，使用两位数；其次是日期，使用两位数；每个都用连字符分隔。 例如，2014 年 1 月 2 日，必须显示为 2014-01-02。 |
| (b) Exceptions. (1) A combination product that properly bears a National Drug Code (NDC) number is not subject to the requirements of paragraph (a) of this section. | (b) 例外情况。 (1) 正确带有国家药品代码 (NDC) 编号的组合产品不受本节 (a) 段要求的约束。 |
| (2) If the device is an electronic product to which a standard is applicable under subchapter J of this chapter, Radiological Health, the date of manufacture shall be presented as required by § 1010.3(a)(2)(ii) of this chapter. | (2) 如果设备是本章第 J 小节“放射健康”下适用标准的电子产品，则应按照本章 §1010.3(a)(2)(ii) 的要求提供 制造日期. |
| **Subpart B - Labeling Requirements for Unique Device Identification** | **B 部分 - 唯一器械标识的标签要求** |
| **Sec. 801.20 Label to bear a unique device identifier.** | **801.20 带有唯一设备标识符的标签。** |
| (a) In general. (1) The label of every medical device shall bear a unique device identifier (UDI) that meets the requirements of this subpart and part 830 of this chapter. | (a)一般而言。 (1) 每个医疗器械的标签都应带有一个唯一的器械标识符（UDI），该标识符符合本章本子部分和第 830 部分的要求。 |
| (2) Every device package shall bear a UDI that meets the requirements of this subpart and part 830 of this chapter. | (2) 每个器械包装都应带有符合本章本子部分和第 830 部分要求的 UDI。 |
| (b) Exceptions. Exceptions to the general rule of paragraph (a) of this section are provided by §§ 801.30, 801.45, and 801.128(f)(2), and § 801.55 provides a means to request an exception or alternative not provided by those provisions. | (b)例外情况。§801.30、801.45 和 §801.128(f)(2) 提供了本节 (a) 段一般规则的例外情况，§ 801.55 提 供了一种请求这些条款未提供的例外或替代方案的方法。 |
| **Sec. 801.30 General exceptions from the requirement for** | **801.30 对设备标签带有唯一设备标识符的要求** |

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| **the label of a device to bear a unique device identifier.** | **的一般例外。** |
| (a) In general. The following types of devices are excepted from the requirement of § 801.20; a device within one or more of the following exceptions is not required to bear a unique device identifier (UDI): | (a) 一般而言。 以下类型的设备不受 § 801.20 的要求；符合以下一种或多种例外情况的设备无需携带唯一设备标识 符 (UDI)： |
| (1) A finished device manufactured and labeled prior to the compliance date established by FDA for § 801.20 regarding the device. This exception expires with regard to a particular device 3 years after the compliance date established by FDA for the device. | (1) 在 FDA 针对 § 801.20 规定的有关设备的合规日期之前制造并贴上标签的成品设备。对于特定设备，此例外在 FDA 为该设备确定的合规日期后 3 年到期。 |
| (2) A class I device that FDA has by regulation exempted from the good manufacturing practice requirements of part 820 of this chapter, exclusive of any continuing requirement for recordkeeping under §§ 820.180 and 820.198. | (2) FDA 根据法规豁免本章第 820 部分的良好生产规范要求的 I 类设备，不包括根据 §§ 820.180 和 820.198 对记录保存的任何持续要求。 |
| (3) Individual single-use devices, all of a single version or model, that are distributed together in a single device package, intended to be stored in that device package until removed for use, and which are not intended for individual commercial distribution. This exception is not available for any implantable device. The device package containing these individual devices is not excepted from the requirement of § 801.20, and must bear a UDI. | (3) 单个一次性设备，所有单个版本或型号，在单个设备包中一起分发，旨在存储在该设备包中直到移除使用，并且不 用于单独的商业分发。此例外不适用于任何可植入设备。包含这些单独设备的设备包不受 § 801.20 的要求的限制，并 且必须带有 UDI。 |
| (4) A device used solely for research, teaching, or chemical analysis, and not intended for any clinical use. | (4) 仅用于研究、教学或化学分析的设备，不用于任何临床用途。 |
| (5) A custom device within the meaning of § 812.3(b) of this chapter. | (5) 本章§ 812.3(b) 含义内的定制设备。 |
| (6) An investigational device within the meaning of part 812 of this chapter. | (6) 本章第 812 部分含义内的研究设备。 |
| (7) A veterinary medical device not intended for use in the diagnosis of disease or other conditions in man, in the cure, mitigation, treatment, or prevention of disease in man, or intended to affect the structure or any function of the body of man. | (7) 非用于诊断人类疾病或其他状况、治愈、缓解、治疗或预防人类疾病，或用于影响人体结构或任何功能的兽用医疗 器械男人。 |
| (8) A device intended for export from the United States. | (8) 打算从美国出口的设备。 |
| (9) A device held by the Strategic National Stockpile and granted an exception or alternative under § 801.128(f)(2). | (9) 由国家战略储备持有并根据 § 801.128(f)(2) 授予例外或替代的设备。 |
| (10) A device for which FDA has established a performance standard under section 514(b) of the Federal Food, Drug, and Cosmetic Act and has provided therein an exception from the requirement of § 801.20, or for which FDA has recognized all or part of a performance standard under section 514(c) of the Federal Food, Drug, and Cosmetic Act and has included an exception from the requirement of § 801.20 within the scope of that recognition. | (10) FDA 根据《联邦食品、药品和化妆品法》第 514(b) 条为其制定了性能标准并在其中规定了 § 801.20 要求的 例外情况的设备，或者 FDA 已经承认所有或联邦食品、药品和化妆品法第 514(c) 节规定的性能标准的一部分，并在该认可范围内包括了 § 801.20 要求的例外情况。 |
| (11) A device packaged within the immediate container of a combination product or convenience kit, provided that the label | (11) 包装在组合产品或便利工具包的直接容器内的设备，前提是组合产品或便利工具包 的标 |

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| of the combination product or convenience kit bears a UDI. | 签带有 UDI。 |
| (b) National Drug Code (NDC) Numbers. If a combination product properly bears an NDC number on its label - | (b)国家药品代码 (NDC) 编号。 如果组合产品在其标签上正确地标有 NDC 编号 - |
| (1) The combination product is not subject to the requirements of § 801.20. | (1) 组合产品不受 § 801.20 的要求。 |
| (2) A device constituent of such a combination product whose components are physically, chemically, or otherwise combined or mixed and produced as a single entity as described by § 3.2(e)(1) of this chapter is not subject to the requirements of § 801.20. | (2) 如本章第 3.2(e)(1) 条所述，组合产品的组成部分通过物理、化学或其他方式组合或混合并作为单一实体生产的 组合产品的器械成分不受以下要求的约束。 § 801.20。 |
| (3) Each device constituent of such a combination product, other than one described by § 3.2(e)(1) of this chapter, must bear a UDI on its label unless paragraph (a)(11) of this section applies. | (3) 除非本节 (a)(11) 段适用，否则此类组合产品的每个设备组成部分，除本章第 3.2(e)(1) 节所述的组成部分 外，必须在其标签上带有 UDI。 |
| (c) Exception for shipping containers. This rule does not require a UDI to be placed on any shipping container. | (c)海运集装箱例外。 此规则不要求将 UDI 放置在任何运输容器上。 |
| (d) The UDI of a class I device is not required to include a production identifier. | (d) I 类器械的 UDI 不需要包括生产标识符。 |
| **Sec. 801.35 Voluntary labeling of a device with a unique device identifier.** | **801.35 使用唯一设备标识符的设备的自愿标签。** |
| (a) The labeler of a device that is not required to bear a unique device identifier (UDI) may voluntarily comply with § 801.20. If a labeler voluntarily includes a UDI for a device, the labeler may voluntarily provide information concerning the device under subpart E of part 830 of this chapter. | (a) 不需要携带唯一设备标识符 (UDI) 的设备的贴标者可以自愿遵守 § 801.20。如果贴标者自愿为器械提供 UDI， 则贴标者可以根据本章第 830 部分的 E 小节自愿提供有关该器械的信息。 |
| (b) A device may bear both a Universal Product Code (UPC) and a UDI on its label and packages. | (b) 设备的标签和包装上可能同时带有通用产品代码 (UPC) 和 UDI。 |
| **Sec. 801.40 Form of a unique device identifier.** | **801.40 唯一设备标识符的形式。** |
| (a) Every unique device identifier (UDI) must meet the technical requirements of § 830.20 of this chapter. The UDI must be presented in two forms: | (a) 每个唯一设备标识符 (UDI) 必须满足本章第 830.20 节的技术要求。UDI 必须以两种形式呈现： |
| (1) Easily readable plain-text, and | (1) 易于阅读的纯文本，以及 |
| (2) Automatic identification and data capture (AIDC) technology. | (2) 自动识别和数据采集（AIDC）技术。 |
| (b) The UDI must include a device identifier segment. Whenever a device label includes a lot or batch number, a serial number, a manufacturing date, an expiration date, or for a human cell, tissue, or cellular or tissue-based product (HCT/P) regulated as a device, a distinct identification code as required by § 1271.290(c) of this chapter, the UDI must include a production identifier segment that conveys such information. | (b) UDI 必须包括设备标识符段。每当器械标签包括批号或批号、序列号、制造日期、到期日期，或者对于作为器械监 管的人体细胞、组织或基于细胞或组织的产品 (HCT/P) 时，一个不同的根据本章 § 1271.290(c) 的要求，UDI 必须包括传达此类信息的生产标识符部分。 |

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| (c) If the AIDC technology is not evident upon visual examination of the label or device package, the label or device package must disclose the presence of AIDC technology. | (c) 如果在视觉检查标签或设备包装时 AIDC 技术不明显，则标签或设备包装必须披露 AIDC 技术的存在。 |
| (d) A class I device that bears a Universal Product Code (UPC) on its label and device packages is deemed to meet all requirements of subpart B of this part. The UPC will serve as the unique device identifier required by § 801.20. | (d) 在其标签和设备包装上带有通用产品代码 (UPC) 的 I 类设备被视为满足本部分 B 子部分的所有要求。UPC 将 作为 § 801.20 要求的唯一设备标识符。 |
| **Sec. 801.45 Devices that must be directly marked with a unique device identifier.** | **801.45 必须直接标有唯一设备标识符的设备。** |
| (a) In general. A device that must bear a unique device identifier (UDI) on its label must also bear a permanent marking providing the UDI on the device itself if the device is intended to be used more than once and intended to be reprocessed before each use. | (a)一般而言。 必须在其标签上带有唯一设备标识符 (UDI) 的设备还必须带有永久性标记，以在设备本身上提供 UDI，如果该设备打算多次使用并打算在每次使用前进行再加工。 |
| (b) UDI for direct marking. The UDI provided through a direct marking on a device may be: | (b)用于直接标记的 UDI。 通过设备上的直接标记提供的 UDI 可能是： |
| (1) Identical to the UDI that appears on the label of the device, or | (1) 与器械标签上出现的 UDI 相同，或 |
| (2) A different UDI used to distinguish the unpackaged device from any device package containing the device. | (2) 一个不同的 UDI，用于将未包装的设备与包含该设备的任何设备包装区分开来。 |
| (c) Form of a UDI when provided as a direct marking. When a device must bear a UDI as a direct marking, the UDI may be provided through either or both of the following: | (c)作为直接标记提供的 UDI 格式。 当设备必须带有 UDI 作为直接标记时，UDI 可以通过以下任何一种或两种方式 提供： |
| (1) Easily readable plain-text; | (1) 易于阅读的纯文本； |
| (2) Automatic identification and data capture (AIDC) technology, or any alternative technology, that will provide the UDI of the device on demand. | (2) 自动识别和数据捕获 (AIDC) 技术，或任何替代技术，将按需提供设备的 UDI。 |
| (d) Exceptions. The requirement of paragraph (a) of this section shall not apply to any device that meets any of the following criteria: | (d)例外情况。 本节 (a) 段的要求不适用于符合以下任何标准的任何设备： |
| (1) Any type of direct marking would interfere with the safety or effectiveness of the device; | (1) 任何类型的直接标记都会干扰器械的安全性或有效性； |
| (2) The device cannot be directly marked because it is not technologically feasible; | (2) 由于技术上不可行，不能直接标记设备； |
| (3) The device is a single-use device and is subjected to additional processing and manufacturing for the purpose of an additional single use. | (3) 该器械为一次性使用器械，为达到额外一次性使用的目的而进行了额外的加工和制造。 |
| (4) The device has been previously marked under paragraph (a) of this section. | (4) 该设备之前已根据本节 (a) 段进行了标记。 |
| (e) Exception to be noted in design history file. A labeler that decides to make use of an exception under paragraph (d of this section) must document the basis of that decision in the design | (e)在设计历史文件中注明的例外情况。 决定根据本节 (d) 段使用例外情况的标签商必须在本章第 820.30(j) 节要 求的设计历史文件中记录该决 |

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| history file required by § 820.30(j) of this chapter. | 定的基础。 |
| **§ 801.50 Labeling requirements for stand-alone software.** | **801.50 独立软件的标签要求。** |
| (a) Stand-alone software that is not distributed in packaged form (e.g., when downloaded from a Web site) is deemed to meet the UDI labeling requirements of this subpart if it complies with the requirements of paragraph (b) of this section and conveys the version number in its production identifier. | (a) 不以打包形式分发的独立软件（例如，从网站下载时）如果符合本节 (b) 段的要求，则被视为满足本小节的 UDI 标签要求，并且在其生产标识符中传达版本号。 |
| (b) Regardless of whether it is or is not distributed in packaged form, stand-alone software regulated as a medical device must provide its unique device identifier through either or both of the following: | (b) 无论是否以打包形式分发，作为医疗器械监管的独立软件必须通过以下任一或两者提供其唯一的器械标识符： |
| (1) An easily readable plain-text statement displayed whenever the software is started; | (1) 软件启动时显示的易于阅读的纯文本语句； |
| (2) An easily readable plain-text statement displayed through a menu command (e.g., an “About * * *” command). | (2) 通过菜单命令（例如，“About * * *”命令）显示的易于阅读的纯文本语句。 |
| (c) Stand-alone software that is distributed in both packaged form and in a form that is not packaged (e.g., when downloaded from a Web site) may be identified with the same device identifier. | (c) 以打包形式和非打包形式分发的独立软件（例如，当从网站下载时）可以用相同的设备标识符来标识。 |
| **§ 801.55 Request for an exception from or alternative to a unique device identifier requirement.** | **801.55 请求对唯一设备标识符要求的例外或替代。** |
| (a) A labeler may submit a request for an exception from or alternative to the requirement of § 801.20 or any other requirement of this subpart for a specified device or a specified type of device. A written request for an exception or alternative must: | (a) 贴标者可以针对特定设备或特定类型的设备提交 § 801.20 要求或本子部分的任何其他要求的例外或替代请求。 例外或替代的书面请求必须： |
| (1) Identify the device or devices that would be subject to the exception or alternative; | (1) 识别可能受到例外或替代的设备； |
| (2) Identify the provisions of this subpart that are the subject of the request for an exception or alternative; | (2) 确定作为例外或替代请求主题的本小节规定； |
| (3) If requesting an exception, explain why you believe the requirements of this subpart are not technologically feasible; | (3) 如果请求例外，请解释您认为本子部分的要求在技术上不可行的原因； |
| (4) If requesting an alternative, describe the alternative and explain why it would provide for more accurate, precise, or rapid device identification than the requirements of this subpart or how the alternative would better ensure the safety or effectiveness of the device that would be subject to the alternative; | (4) 如果要求替代方案，请描述替代方案并解释为什么它会比本子部分的要求提供更准确、准确或快速的设备识别，或 者替代方案如何更好地确保设备的安全性或有效性。以替代方案为准； |
| (5) Provide, if known, the number of labelers and the number of devices that would be affected if we grant the requested exception or alternative; and | (5) 提供（如果已知）标签机的数量和如果我们批准请求的例外或替代方案将受到影响的设备数量；和 |
| (6) Provide other requested information that the Center Director needs to clarify the scope and effects of the requested exception or alternative. | (6) 提供中心主任需要澄清请求的例外或替代方案的范围和影响的其他请求信息。 |

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| (b) A written request for an exception or alternative must be submitted by sending it: | (b) 例外或替代的书面请求必须通过以下方式提交： |
| (1) If the device is regulated by the Center for Biologics Evaluation and Research (CBER), by email to: cberudirequests@fda.hhs.gov or by correspondence to: Food and Drug Administration, Center for Biologics Evaluation and Research, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G112, Silver Spring, MD 20993. | (1) 如果设备受生物制品评估和研究中心 (CBER) 监管，请通过电子邮件发送至：cberudirequests@fda.hhs.gov 或通过信件发送至：食品和药物管理局、生物制品评估和研究中心、文件控制中心，10903 New Hampshire Ave., Bldg. 71 室。G112，银泉，MD 20993。 |
| (2) In all other cases, by email to: GUDIDSupport@fda.hhs.gov, or by correspondence to: UDI Regulatory Policy Support, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 3293, Silver Spring, MD 20993-0002. | (2) 在所有其他情况下，通过电子邮件发送至：GUDIDSupport@fda.hhs.gov， 或通过信件发送至：UDI 监管政策 支持，设备和放射健康中心，食品和药物管理局，10903 New Hampshire Ave., Bldg。32 室。3293，银泉，MD 20993-0002。 |
| (c) The Center Director may grant an exception or alternative, either in response to a request or on his or her own initiative, if the Center Director determines that an exception is appropriate because the requirements of this subpart are not technologically feasible, or that an alternative would provide for more accurate, precise, or rapid device identification than the requirements of this subpart or would better ensure the safety or effectiveness of the device that would be subject to the alternative. If we grant an exception or alternative, we may include any safeguards or conditions deemed appropriate to ensure the adequate identification of the device through its distribution and use. Any labeler may make use of an exception or alternative granted under this section, provided that such use satisfies all safeguards or conditions that are part of the exception or alternative. | (c) 如果中心主任确定例外是适当的，因为本子部分的要求在技术上不可行，或者中心主任可以响应请求或主动授予例 外或替代替代方案将提供比本子部分的要求更准确、精确或快速的设备识别，或将更好地确保受替代方案约束的设备的 安全性或有效性。如果我们授予例外或替代方案，我们可能会包括任何被认为适当的保障措施或条件，以确保通过其分 发和使用对设备进行充分识别。任何贴标者都可以利用根据本节授予的例外或替代方案， |
| (d) FDA may initiate and grant an exception or alternative if we determine that the exception or alternative is in the best interest of the public health. Any such exception or alternative will remain in effect only so long as there remains a public health need for the exception or alternative | (d) 如果我们确定例外或替代方案符合公众健康的最佳利益，FDA 可以启动和批准例外或替代方案。任何此类例外或替 代方案只有在公共卫生需要例外或替代方案时才会继续有效。 |
| (e) The Center Director may rescind an exception or alternative granted under this section if, after providing an opportunity for an informal hearing as defined in section 201(x) of the Federal Food, Drug, and Cosmetic Act and under part 16 of this chapter, the Center Director determines that the exception or alternative no longer satisfies the criteria described in this paragraph (e) or that any safeguard or condition required under this paragraph (e) has not been met. | (e) 如果在提供了联邦食品、药品和化妆品法第 201(x) 节和本法第 16 部分规定的非正式听证会的机会后，中心主 任可以撤销根据本节授予的例外或替代方案章，中心主任确定例外或替代方案不再满足本段 (e) 中描述的标准，或者 本段 (e) 要求的任何保障措施或条件未得到满足。 |
| **§ 801.57 Discontinuation of legacy FDA identification numbers assigned to devices.** | **801.57 终止分配给设备的传统 FDA 识别号。** |
| (a) On the date your device must bear a unique device identifier (UDI) on its label, any National Health-Related Item Code (NHRIC) or National Drug Code (NDC) number assigned to that device is rescinded, and you may no longer provide an NHRIC or NDC number on the label of your device or on any device | (a) 自您的设备必须在其标签上带有唯一设备标识符 (UDI) 之日起，分配给该设备的任何国家健康相关项目代码 (NHRIC) 或国家药品代码 (NDC) 编号都将被撤销，您不得不再在您的设 |

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| package. | 备标签或任何设备包装上提供 NHRIC 或 NDC 编号。 |
| (b) If your device is not required to bear a UDI on its label, any NHRIC or NDC number assigned to that device is rescinded as of September 24, 2018, and beginning on that date, you may no longer provide an NHRIC or NDC number of the label of your device or on any device package. | (b) 如果您的设备不需要在其标签上贴有 UDI，则分配给该设备的任何 NHRIC 或 NDC 编号都将自 2018 年 9 月 24 日起撤销，并且从该日期开始，您可能不再提供 NHRIC 或 NDC设备标签或任何设备包装上的编号。 |
| (c) A labeler who has been assigned an FDA labeler code to facilitate use of NHRIC or NDC numbers may continue to use that labeler code under a system for the issuance of UDIs, provided that - | (c) 为方便使用 NHRIC 或 NDC 编号而分配了 FDA 标记代码的标记者可以继续在颁发 UDI 的系统下使用该标记代 码，前提是： |
| (1) Such use is consistent with the framework of the issuing agency that operates that system; and | (1) 此类使用与运行该系统的发行机构的框架一致；和 |
| (2) No later than September 24, 2014, the labeler submits, and obtains FDA approval of, a request for continued use of the assigned labeler code. A request for continued use of an assigned labeler code must be submitted by email to: GUDIDSupport@fda.hhs.gov, or by correspondence to: UDI Regulatory Policy Support, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 3293, Silver Spring, MD 20993-0002. | (2) 不迟于 2014 年 9 月 24 日，贴标者提交并获得 FDA 批准，继续使用指定的贴标者代码的请求。继续使用指定 标签代码的请求必须通过电子邮件提交至：GUDIDSupport@fda.hhs.gov， 或通过信件提交至：UDI 监管政策支持， 设备和放射健康中心，食品和药物管理局，10903 New Hampshire大道，大厦。32 室。3293，银泉，MD 20993- 0002。 |
| (d) Each request for continued use of an assigned labeler code must provide - | (d) 继续使用指定标签代码的每个请求必须提供 - |
| (1) The name, mailing address, email address, and phone number of the labeler who is currently using the labeler code; | (1) 当前使用贴标人代码的贴标人的姓名、邮寄地址、电子邮件地址和电话号码； |
| (2) The owner/operator account identification used by the labeler to submit registration and listing information using FDA's Unified Registration and Listing System (FURLS). | (2) 贴标者使用 FDA 的统一注册和列名系统 (FURLS) 提交注册和列名信息时使用的所有者/经营者帐户标识。 |
| (3) The FDA labeler code that the labeler wants to continue using. | (3) 贴标者希望继续使用的 FDA 贴标者代码。 |
| Subpart C - Labeling Requirements for Over-the-Counter Devices | 子部分 C - 非处方设备的标签要求 |
| **§ 801.60 Principal display panel.** | **801.60 主显示面板。** |
| The term principal display panel, as it applies to over-the-counter devices in package form and as used in this part, means the part of a label that is most likely to be displayed, presented, shown, or examined under customary conditions of display for retail sale. The principal display panel shall be large enough to accommodate all the mandatory label information required to be placed thereon by this part with clarity and conspicuousness and without obscuring designs, vignettes, or crowding. Where packages bear alternate principal display panels, information required to be placed on the principal display panel shall be | 术语“主展示板 ”适用于包装形式的非处方药并在本部分中使用，是指标签中最有可能在以下惯常条件下展示、显示、呈现或检查的部分。零售展示。主显示面板应足够大，以容纳该部分要求放置在其上的所有强制性标签信息，清晰、醒 目，并且不会模糊设计、晕影或拥挤。如果包装带有备用主展示板，则需要在主展示板上放置的信息应在每个主展示板 上复制。为 |

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| duplicated on each principal display panel. For the purpose of obtaining uniform type size in declaring the quantity of contents for all packages of substantially the same size, the term area of the principal display panel means the area of the side or surface that bears the principal display panel, which area shall be: | 了在声明所有基本相同尺寸的包装的内容量时获得统一的字体尺寸，术语主显示面板 的面积是指承载主显示 面板的侧面或表面的面积，该面积应为： |
| (a) In the case of a rectangular package where one entire side properly can be considered to be the principal display panel side, the product of the height times the width of that side; | (a) 在矩形包装的情况下，一个整边适当地可以被认为是主要的展示面板边，高度乘以该边的宽度的乘积； |
| (b) In the case of a cylindrical or nearly cylindrical container, 40 percent of the product of the height of the container times the circumference; and | (b) 对于圆柱形或近似圆柱形容器，容器高度乘以周长的乘积的 40%；和 |
| (c) In the case of any other shape of container, 40 percent of the total surface of the container: Provided, however, That where such container presents an obvious “principal display panel” such as the top of a triangular or circular package, the area shall consist of the entire top surface. | (c) 对于任何其他形状的容器，占容器总表面的 40%：但是， 如果该容器具有明显的“主要展示面板”，例如三角形或 圆形包装的顶部，该区域应包括整个顶面。 |
| In determining the area of the principal display panel, exclude tops, bottoms, flanges at the tops and bottoms of cans, and shoulders and necks of bottles or jars. In the case of cylindrical or nearly cylindrical containers, information required by this part to appear on the principal display panel shall appear within that 40 percent of the circumference which is most likely to be displayed, presented, shown, or examined under customary conditions of display for retail sale. | 在确定主要展示面板的面积时，不包括顶部、底部、罐头和底部的法兰以及瓶子或罐子的肩部和颈部。对于圆柱形或接 近圆柱形的容器，本部分要求出现在主展示板上的信息应出现在最有可能在常规展示条件下展示、呈现、展示或检查的 圆周的 40% 内用于零售。 |
| **§ 801.61 Statement of identity.** | **801.61 身份声明。** |
| (a) The principal display panel of an over-the-counter device in package form shall bear as one of its principal features a statement of the identity of the commodity. | (a) 包装形式的非处方药的主要展示面板应以商品身份声明作为其主要特征之一。 |
| (b) Such statement of identity shall be in terms of the common name of the device followed by an accurate statement of the principal intended action(s) of the device. Such statement shall be placed in direct conjunction with the most prominent display of the name and shall employ terms descriptive of the principal intended action(s). The indications for use shall be included in the directions for use of the device, as required by section 502(f)(1) of the act and by the regulations in this part. | (b) 此类身份声明应使用设备的通用名称，然后是设备主要预期操作的准确声明。此类声明应与最显眼的名称直接结合 放置，并应使用描述主要预期行动的术语。根据法案第 502(f)(1) 节和本部分的规定，使用说明应包含在设备的使用 说明中。 |
| (c) The statement of identity shall be presented in bold face type on the principal display panel, shall be in a size reasonably related to the most prominent printed matter on such panel, and shall be in lines generally parallel to the base on which the package rests as it is designed to be displayed. | (c) 身份声明应在主展示板上以粗体字显示，其尺寸应与该板上最显眼的印刷品合理相关，并应与基本平行的行包装休 息，因为它被设计为显示。 |
| **§ 801.62 Declaration of net quantity of contents.** | **801.62 内容净量声明。** |
| (a) The label of an over-the-counter device in package form shall bear a declaration of the net quantity of contents. This shall be expressed in the terms of weight, measure, numerical count, or a combination of numerical count and weight, measure, or size: Provided, That: | (a) 包装形式的非处方药的标签应标明内容物的净含量。这应以重量、尺寸、数字计数或数字计数与重量、尺寸或尺寸 的组合表示：前提是： |
| (1) In the case of a firmly established general consumer usage | (1) 在已确立的一般消费者习惯和贸易习惯的情 |

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| and trade custom of declaring the quantity of a device in terms of linear measure or measure of area, such respective term may be used. Such term shall be augmented when necessary for accuracy of information by a statement of the weight, measure, or size of the individual units or of the entire device. | 况下，以线性度量或面积度量来声明设备的数量，可以使用相应的术 语。必要时，应通过对单个单元或整个设备的重量、尺寸或尺寸的说明来增加信息的准确性。 |
| (2) If the declaration of contents for a device by numerical count does not give accurate information as to the quantity of the device in the package, it shall be augmented by such statement of weight, measure, or size of the individual units or of the total weight, measure, or size of the device as will give such information; for example, “100 tongue depressors, adult size”, “1 rectal syringe, adult size”, etc. Whenever the Commissioner determines for a specific packaged device that an existing practice of declaring net quantity of contents by weight, measure, numerical count, or a combination of these does not facilitate value comparisions by consumers, he shall by regulation designate the appropriate term or terms to be used for such article. | (2) 如果以数字计数的器械内容声明未提供关于包装中器械数量的准确信息，则应在声明中补充单个单元的重量、尺寸 或尺寸或提供此类信息的设备的总重量、尺寸或尺寸；例如，“100 个压舌板，成人尺寸”、“1 个直肠注射器，成人尺 寸”等。或这些的组合不利于消费者进行价值比较，他应通过法规指定用于此类物品的适当术语或术语。 |
| (b) Statements of weight of the contents shall be expressed in terms of avoirdupois pound and ounce. A statement of liquid measure of the contents shall be expressed in terms of the U.S. gallon of 231 cubic inches and quart, pint, and fluid-ounce subdivisions thereof, and shall express the volume at 68 °F (20 °C). See also paragraph (p) of this section. | (b) 内容物的重量声明应以 avoirdupois 磅和盎司表示。内容物的液体量度声明应以美制加仑 231 立方英寸及其夸 脱、品脱和液量盎司细分表示，并应表示 68 华氏度（20 摄氏度）时的体积。另见本节 (p) 段。 |
| (c) The declaration may contain common or decimal fractions. A common fraction shall be in terms of halves, quarters, eighths, sixteenths, or thirty-seconds; except that if there exists a firmly established, general consumer usage and trade custom of employing different common fractions in the net quantity declaration of a particular commodity, they may be employed. A common fraction shall be reduced to its lowest terms; a decimal fraction shall not be carried out to more than two places. A statement that includes small fractions of an ounce shall be deemed to permit smaller variations than one which does not include such fractions. | (c) 声明可以包含常用或小数部分。一个共同的分数应该是一半，四分之一，八分之一，十六分之一，或三十秒；除非 存在牢固确立的一般消费者习惯和贸易习惯，即在特定商品的净数量申报中使用不同的常用分数，则可以使用它们。共 同分数应简化为最低项；小数不得超过两位。包含小部分盎司的声明应被视为允许比不包含此类小部分的声明更小的变 化。 |
| (d) The declaration shall be located on the principal display panel of the label, and with respect to packages bearing alternate principal panels it shall be duplicated on each principal display panel. | (d) 声明应位于标签的主显示面板上，对于带有交替主面板的包装，声明应在每个主显示面板上复制。 |
| (e) The declaration shall appear as a distinct item on the principal display panel, shall be separated, by at least a space equal to the height of the lettering used in the declaration, from other printed label information appearing above or below the declaration and, by at least a space equal to twice the width of the letter “N” of the style of type used in the quantity of contents statement, from other printed label information appearing to the left or right of the declaration. It shall not include any term qualifying a unit of weight, measure, or count, such as “giant pint” and “full quart”, that tends to exaggerate. It shall be placed on the principal display panel within the bottom 30 percent of the area of the label panel in lines generally parallel to the base on which the package rests as it is designed to be displayed: Provided, That: | (e) 声明应作为独立项目出现在主显示面板上，与声明上方或下方出现的其他印刷标签信息之间的间距至少等于声明中 使用的字母的高度，并且, 与出现在声明左侧或右侧的其他印刷标签信息之间的距离至少等于内容数量声明中使用的字 体样式的字母“N”宽度的两倍。它不应包括任何限定重量、度量或计数单位的术语，例如“大品脱”和“整夸脱”，这往往 会夸大其词。前提是： |

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| (1) On packages having a principal display panel of 5 square inches or less the requirement for placement within the bottom 30 percent of the area of the label panel shall not apply when the declaration of net quantity of contents meets the other requirements of this part; and | (1) 在主显示面板小于等于 5 平方英寸的包装上，当内容物的净含量声明符合本部分的其他要求时，不适用放置在标 签面板底部 30% 区域内的要求; 和 |
| (2) In the case of a device that is marketed with both outer and inner retail containers bearing the mandatory label information required by this part and the inner container is not intended to be sold separately, the net quantity of contents placement requirement of this section applicable to such inner container is waived. | (2) 对于外包装和内包装均带有本部分要求的强制性标签信息且内容器不打算单独销售的器械，本节内容物放置要求的 净数量适用于该内容器的豁免。 |
| (3) The principal display panel of a device marketed on a display card to which the immediate container is affixed may be considered to be the display panel of the card, and the type size of the net quantity of contents statement is governed by the dimensions of the display card. | (3) 贴有直接容器的显示卡上销售的器械的主显示面板可视为卡片的显示面板，内容物净量声明的字体大小以尺寸为准 的显示卡。 |
| (f) The declaration shall accurately reveal the quantity of device in the package exclusive of wrappers and other material packed therewith. | (f) 声明应准确显示包装中设备的数量，不包括包装纸和其他包装材料。 |
| (g) The declaration shall appear in conspicuous and easily legible boldface print or type in distinct contrast (by typography, layout, color, embossing, or molding) to other matter on the package; except that a declaration of net quantity blown, embossed, or molded on a glass or plastic surface is permissible when all label information is so formed on the surface. Requirements of conspicuousness and legibility shall include the specifications that: | (g) 声明应以醒目易读的粗体印刷或与包装上的其他内容形成明显对比（通过版式、布局、颜色、压花或模制）的类型 出现；但当所有标签信息都如此形成在玻璃或塑料表面上时，允许声明在玻璃或塑料表面上吹制、压花或模制的净数 量。醒目性和易读性要求应包括以下规格： |
| (1) The ratio of height to width of the letter shall not exceed a differential of 3 units to 1 unit, i.e., no more than 3 times as high as it is wide. | (1) 字母的高宽比不得超过3个单位比1个单位的差值，即不超过其宽度的3倍。 |
| (2) Letter heights pertain to upper case or capital letters. When upper and lower case or all lower case letters are used, it is the lower case letter “o” or its equivalent that shall meet the minimum standards. | (2) 字母高度与大写或大写字母有关。当使用大小写字母或全部小写字母时，小写字母“o”或其等效字母应符合最低标 准。 |
| (3) When fractions are used, each component numeral shall meet one-half the minimum height standards. | (3) 使用分数时，每个分量数字应满足最小高度标准的二分之一。 |
| (h) The declaration shall be in letters and numerals in a type size established in relationship to the area of the principal display panel of the package and shall be uniform for all packages of substantially the same size by complying with the following type specifications: | (h) 声明应采用字母和数字，其字体尺寸与包装件主显示面板的面积有关，并且对于所有尺寸基本相同的包装件，应符 合以下字体规格： |
| (1) Not less than one-sixteenth inch in height on packages the principal display panel of which has an area of 5 square inches or less. | (1) 主显示面板面积不超过 5 平方英寸的包装上，高度不少于十六分之一英寸。 |
| (2) Not less than one-eighth inch in height on packages the principal display panel of which has an area of more than 5 but not more than 25 square inches. | (2) 主显示面板面积大于 5 平方英寸但不大于 25 平方英寸的包装件的高度不少于八分之一英寸。 |
| (3) Not less than three-sixteenths inch in height on packages the | (3) 主显示面板面积大于 25 平方英寸但不大于 |

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| principal display panel of which has an area of more than 25 but not more than 100 square inches. | 100 平方英寸的包装件的高度不少于十六分之三英寸。 |
| (4) Not less than one-fourth inch in height on packages the principal display panel of which has an area of more than 100 square inches, except not less than one-half inch in height if the area is more than 400 square inches. | (4) 主显示面板面积超过 100 平方英寸的包装，高度不少于四分之一英寸，但面积超过 400 平方英寸的，高度不低 于二分之一英寸。 |
| Where the declaration is blown, embossed, or molded on a glass or plastic surface rather than by printing, typing, or coloring, the lettering sizes specified in paragraphs (h)(1) through (4) of this section shall be increased by one-sixteenth of an inch. | 如果声明是在玻璃或塑料表面吹制、压印或模压而不是通过印刷、打字或着色，则本节 (h)(1) 至 (4) 中规定的字母 尺寸应增加一- 十六分之一英寸。 |
| (i) On packages containing less than 4 pounds or 1 gallon and labeled in terms of weight or fluid measure: | (i) 在包含少于 4 磅或 1 加仑并以重量或液体量度标注的包装上： |
| (1) The declaration shall be expressed both in ounces, with identification by weight or by liquid measure and, if applicable (1 pound or 1 pint or more) followed in parentheses by a declaration in pounds for weight units, with any remainder in terms of ounces or common or decimal fractions of the pound (see examples set forth in paragraphs (k) (1) and (2) of this section), or in the case of liquid measure, in the largest whole units (quarts, quarts and pints, or pints, as appropriate) with any remainder in terms of fluid ounces or common or decimal fractions of the pint or quart (see examples set forth in paragraphs (k) (3) and (4) of this section). If the net weight of the package is less than 1 ounce avoirdupois or the net fluid measure is less than 1 fluid ounce, the declaration shall be in terms of common or decimal fractions of the respective ounce and not in terms of drams. | (1) 声明应以盎司表示，并以重量或液体计量标识，如果适用（1 磅或 1 品脱或更多），则在括号中加上以磅为单位 的重量声明，其余部分以术语表示盎司或英镑的普通或小数部分（参见本节第 (k) (1) 和 (2) 段中列出的示例）， 或在液体量度的情况下，以最大的整数单位（夸脱、夸脱和品脱或品脱，视情况而定）以及以液量盎司或品脱或夸脱的 普通或小数部分表示的任何余数（参见本节第 (k) (3) 和 (4) 段中列出的示例）。如果包装的净重小于 1 盎司 avoirdupois 或净液量小于 1 液量盎司， |
| (2) The declaration may appear in more than one line. The term “net weight” shall be used when stating the net quantity of contents in terms of weight. Use of the terms “net” or “net contents” in terms of fluid measure or numerical count is optional. It is sufficient to distinguish avoirdupois ounce from fluid ounce through association of terms; for example, “Net wt. 6 oz” or “6 oz net wt.,” and “6 fl oz” or “net contents 6 fl oz.” | (2) 声明可能出现在多于一行。以重量表示内容物的净含量时，应使用“净重”一词。在流体测量或数字计数方面使用术 语“净”或“净含量”是可选的。通过术语的关联来区分avoirdupois ounce和fluid ounce就足够了；例如，“净重 6 盎司”或“6 盎司净重”和“6 液量盎司”或“净含量 6 液量盎司”。 |
| (j) On packages containing 4 pounds or 1 gallon or more and labeled in terms of weight or fluid measure, the declaration shall be expressed in pounds for weight units with any remainder in terms of ounces or common or decimal fractions of the pound; in the case of fluid measure, it shall be expressed in the largest whole unit, i.e., gallons, followed by common or decimal fractions of a gallon or by the next smaller whole unit or units (quarts or quarts and pints), with any remainder in terms of fluid ounces or common or decimal fractions of the pint or quart; see paragraph (k)(5) of this section. | (j) 在包含 4 磅或 1 加仑或更多且以重量或流体量度标记的包装上，声明应以磅表示重量单位，任何余数以盎司或磅 的常用或小数部分表示；在流体测量的情况下，它应以最大的整数单位表示，即加仑，然后是加仑的常见或小数部分， 或者是下一个更小的整数单位或单位（夸脱或夸脱和品脱），以及任何余数以液量盎司或品脱或夸脱的普通或小数部分 表示；见本节第 (k)(5) 段。 |
| (k) Examples: | (k)示例： |
| (1) A declaration of 11⁄2 pounds weight shall be expressed as “net wt. 24 oz (1 lb 8 oz),” or “Net wt. 24 oz (11⁄2 lb)” or “Net wt. | (1) 1 1/2 磅重量的声明应表示为“净重 24 盎司（1 磅 8 盎司）”或“净重 24 盎司（1 1/2 磅）” |

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| 24 oz (1.5 lb)." | 或 "净重 24 盎司（1.5 磅）"。 |
| (2) A declaration of three-fourths pound avoirdupois weight shall be expressed as "Net wt. 12 oz.". | (2) 四分之三磅重的声明应表示为"净重 12 盎司"。 |
| (3) A declaration of 1 quart liquid measure shall be expressed as "Net contents 32 fl oz (1 qt)" or "32 fl oz (1 qt)." | (3) 1 夸脱液体量度的声明应表示为"净含量 32 液量盎司（1 夸脱）"或"32 液量盎司（1 夸脱）"。 |
| (4) A declaration of 13 ⁄4 quarts liquid measure shall be expressed as, "Net contents 56 fl oz (1 qt 1 pt 8 oz)" or "Net contents 56 fl oz (1 qt 1.5 pt)," but not in terms of quart and ounce such as "Net contents 56 fl oz (1 qt 24 oz)." | (4) 1 3/4 夸脱液体量度的声明应表示为"净含量 56 液量盎司（1 夸脱 1 磅 8 盎司）"或"净含量 56 液量盎司 （1 夸脱 1.5 磅）"，但不是以夸脱和盎司为单位，例如"净含量 56 液量盎司（1 夸脱 24 盎司）"。 |
| (5) A declaration of 21 ⁄2 gallons liquid measure shall be expressed as "Net contents 2 gal 2 qt", "Net contents 2.5 gallons," or "Net contents 21⁄2 gal" but not as "2 gal 4 pt". | (5) 2 1/2 加仑液体量度的声明应表示为"净含量 2 加仑 2 夸脱"、"净含量 2.5 加仑"或"净含量 2 1/2 加仑"， 但不能表示为"2 加仑 4点"。 |
| (l) For quantities, the following abbreviations and none other may be employed. Periods and plural forms are optional: | (l) 对于数量，可以使用以下缩写，不得使用其他缩写。句号和复数形式是可选的： |

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| gallon gal | liter l |
| milliliter ml | cubic centimeter cc |
| quart qt | yard yd |
| pint pt | feet or foot ft |
| ounce oz | inch in |
| pound lb | meter m |
| grain gr | centimeter cm |
| kilogram kg | millimeter mm |
| gram g | fluid f |
| milligram mg | square sq |
| microgram mcg | weight wt |

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| 加仑加仑 | 升 l |
| 毫升毫升 | 立方厘米 cc |
| 夸脱 | 码码 |
| 品脱 | 英尺或英尺 |
| 盎司盎司 | 英寸 |
| 磅磅 | 米米 |
| 五谷杂粮 | 厘米 厘米 |
| 公斤公斤 | 毫米毫米 |
| 克 | 流体流动 |
| 毫克毫克 | 平方 |
| 微克 mcg | 重量 wt |

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| (m) On packages labeled in terms of linear measure, the declaration shall be expressed both in terms of inches and, if applicable (1 foot or more), the largest whole units (yards, yards and feet, feet). The declaration in terms of the largest whole units shall be in parentheses following the declaration in terms of inches and any remainder shall be in terms of inches or common or decimal fractions of the foot or yard; if applicable, as in the case of adhesive tape, the initial declaration in linear inches shall be preceded by a statement of the width. Examples of linear measure are "86 inches (2 yd 1 ft 2 in)", "90 inches (21 ⁄2 yd)", "30 inches (2.5 ft)", " 3⁄4 inch by 36 in (1 yd)", etc. | (m) 在以直线尺寸标注的包装上，声明应以英寸表示，如果适用（1 英尺或更多），则以最大的整体单位（码、码和英 尺、英尺）表示。以最大整体单位表示的声明应以英寸为单位的声明后的括号中，其余部分应以英寸或英尺或码的常用 或小数部分表示；如果适用，如在胶带的情况下，以线性英寸为单位的初始声明之前应声明宽度。线性测量的示例是"86 英寸（2 码 1 英尺 2 英寸）"、"90 英寸（2 1/2 码）"、"30 英寸（2.5 英尺）"、"3/4 英寸 x 36 英寸（1 码）" ）"， ETC。 |

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| (n) On packages labeled in terms of area measure, the declaration shall be expressed both in terms of square inches and, if applicable (1 square foot or more), the largest whole square unit (square yards, square yards and square feet, square feet). The declaration in terms of the largest whole units shall be in parentheses following the declaration in terms of square inches and any remainder shall be in terms of square inches or common or decimal fractions of the square foot or square yard; for example, “158 sq inches (1 sq ft 14 sq in)”. | (n) 在以面积计量标记的包装上，声明应以平方英寸和（如适用）（1 平方英尺或更多）最大整平方单位（平方码、平 方码和平方英尺，平方英尺）。最大整体单位的声明应以平方英寸的形式在声明后的括号中，其余部分应以平方英寸或 平方英尺或平方码的常用或小数部分表示；例如，“158 平方英寸（1 平方英尺 14 平方英寸）”。 |
| (o) Nothing in this section shall prohibit supplemental statements at locations other than the principal display panel(s) describing in nondeceptive terms the net quantity of contents, provided that such supplemental statements of net quantity of contents shall not include any term qualifying a unit of weight, measure, or count that tends to exaggerate the amount of the device contained in the package; for example, “giant pint” and “full quart”. Dual or combination declarations of net quantity of contents as provided for in paragraphs (a) and (i) of this section are not regarded as supplemental net quantity statements and shall be located on the principal display panel. | (o) 本节中的任何内容均不得禁止在主显示面板以外的位置进行补充声明，以非欺骗性的方式描述内容的净数量，前提 是此类内容净数量的补充声明不应包括任何限定单位的术语倾向于夸大包装中包含的设备数量的重量、尺寸或计数；例 如，“giant pint”和“full quart”。本条(a)和(i)款规定的双重或组合净含量声明不作为补充净含量声明，应位于 主显示面板上。 |
| (p) A separate statement of net quantity of contents in terms of the metric system of weight or measure is not regarded as a supplemental statement and an accurate statement of the net quantity of contents in terms of the metric system of weight or measure may also appear on the principal display panel or on other panels. | (p) 单独的以重量或计量单位表示的净含量不作为补充说明，以重量或计量单位准确表示的净含量也可以出现在主显示 面板或其他面板上。 |
| (q) The declaration of net quantity of contents shall express an accurate statement of the quantity of contents of the package. Reasonable variations caused by loss or gain of moisture during the course of good distribution practice or by unavoidable deviations in good manufacturing practice will be recognized. Variations from stated quantity of contents shall not be unreasonably large. | (q) 内容物净含量声明应准确表述包装内容物的数量。在良好分销实践过程中由水分损失或获得或由良好生产实践中不 可避免的偏差引起的合理变化将被识别。与规定的内容量的差异不应过大。 |
| § 801.63 Medical devices; warning statements for devices containing or manufactured with chlorofluorocarbons and other class I ozone-depleting substances. | 801.63 医疗器械；含有或用氯氟烃和其他 I 类消耗臭氧物质制造的设备的警告声明。 |
| (a) All over-the-counter devices containing or manufactured with chlorofluorocarbons, halons, carbon tetrachloride, methyl chloride, or any other class I substance designated by the Environmental Protection Agency (EPA) shall carry one of the following warnings: | (a) 所有含有氯氟烃、哈龙、四氯化碳、氯甲烷或环境保护署 (EPA) 指定的任何其他 I 类物质或由其制造的非处方 设备都应带有以下警告之一： |
| (1)The EPA warning statement:<br>WARNING: Contains [or Manufactured with, if applicable] [insert name of substance], a substance which harms public health and environment by destroying ozone in the upper atmosphere. | (1)EPA 警告声明：<br>警告：包含 [或制造，如果适用] [插入物质名称]，一种通过破坏高层大气中的臭氧来危害公众健康和环境的物质。 |
| (2) The alternative statement: | (2) 替代陈述： |
| (b) The warning statement shall be clearly legible and conspicuous on the product, its immediate container, its outer packaging, or other labeling in accordance with the | (b) 根据 40 CFR 第 82 部分的要求，警告声明应在产品、其直接容器、外包装或其他标签上 |

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| requirements of 40 CFR part 82 and appear with such prominence and conspicuousness as to render it likely to be read and understood by consumers under normal conditions of purchase. This provision does not replace or relieve a person from any requirements imposed under 40 CFR part 82. | 清晰易读且醒目，并以 使其可能消费者在正常购买条件下阅读和理解。该规定不能替代或免除个人根据 40 CFR 第 82 部分施加的任何要求。 |
| Note:<br>The indented statement below is required by the Federal government's Clean Air Act for all products containing or manufactured with chlorofluorocarbons (CFC's) [or other class I substance, if applicable]:<br>WARNING: Contains [or Manufactured with, if applicable] [insert name of substance], a substance which harms public health and environment by destroying ozone in the upper atmosphere.<br>CONSULT WITH YOUR PHYSICIAN, HEALTH PROFESSIONAL, OR SUPPLIER IF YOU HAVE ANY QUESTION ABOUT THE USE OF THIS PRODUCT. | 笔记：<br>联邦政府的《清洁空气法》要求所有含有或使用氯氟烃 (CFC) [或其他 I 类物质，如果适用] 的产品制造以下缩进声 明：<br>警告：包含 [或制造，如果适用] [插入物质名称]，一种通过破坏高层大气中的臭氧来危害公众健康和环境的物质。<br>如果您对本产品的使用有任何疑问，请咨询您的医生、健康专家或供应商。 |
| **Subpart D - Exemptions From Adequate Directions for Use** | **D部分 - 充分使用说明的豁免** |
| **§ 801.109 Prescription devices.** | **801.109 处方设备。** |
| 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 such device, and hence for which “adequate directions for use” cannot be prepared, shall be exempt from section 502(f)(1) of the act if all the following conditions are met: | 由于任何潜在的有害影响或其使用方法或其使用所必需的附带措施而不安全的设备，除非在获得法律许可以指导使用此 类设备的从业者的监督下，因此如果满足以下所有条件，则无法为其准备“充分的使用说明”，则应免除该法第 502(f) (1) 条的规定： |
| (a) The device is: | (a) 该设备是： |
| (1) (i) In the possession of a person, or his agents or employees, regularly and lawfully engaged in the manufacture, transportation, storage, or wholesale or retail distribution of such device; or | (1)(i) 由个人或其代理人或雇员持有，定期合法地从事此类设备的制造、运输、储存或批发或零售分销；或者 |
| (ii) In the possession of a practitioner, such as physicians, dentists, and veterinarians, licensed by law to use or order the use of such device; and | (ii) 由获得法律许可使用或命令使用此类设备的执业医师（例如医师、牙医和兽医）持有；和 |
| (2) Is to be sold only to or on the prescription or other order of such practitioner for use in the course of his professional practice. | (2) 仅出售给该从业者或根据该从业者的处方或其他命令出售，以便在其专业实践过程中使用。 |
| (b) The label of the device, other than surgical instruments, bears: | (b) 除手术器械外，该器械的标签带有： |
| (1) The symbol statement “Rx only” or “? only” or 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”, “veterinarian”, or with the descriptive designation of any other practitioner licensed by the law of the State in which the practitioner practices to use or order the use of the device; and | (1) 符号声明“Rx only”或“â?? only”或声明“注意：联邦法律限制此设备只能由 ___ 或按订单销售”，空白处填写 “医师”一词”、“牙医”、“兽医”，或具有从业者实践使用或命令使用该设备的州的法律许可的任何其他从业者的描述性 名称；和 |

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| (2) The method of its application or use. | (2) 其应用或使用方法。 |
| (c) Labeling on or within the package from which the device is to be dispensed bears information for use, including indications, effects, routes, methods, and 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: Provided, however, That such information may be omitted from the dispensing package if, but only if, the article is a device for which directions, hazards, warnings, and other information are commonly known to practitioners licensed by law to use the device. Upon written request, stating reasonable grounds therefor, the Commissioner will offer an opinion on a proposal to omit such information from the dispensing package under this proviso. | (c) 用于分配器械的包装上或包装内的标签包含使用信息，包括适应症、效果、途径、方法、给药频率和持续时间，以 及任何相关的危害、禁忌症、副作用和预防措施根据该规定，获得法律许可管理该设备的从业人员可以安全地使用该设 备并用于其预期目的，包括其广告或代表的所有目的：但是，前提是， 当但仅当物品是一种器械，其说明、危险、警告 和其他信息为依法许可使用该器械的从业者所熟知时，可以从分配包装中省略此类信息。应书面请求并说明合理理由， 专员将就根据本但书从配药包中省略此类信息的提议提出意见。 |
| (d) Any labeling, as defined in section 201(m) of the act, whether or not it is on or within a package from which the device is to be dispensed, distributed by or on behalf of the manufacturer, packer, or distributor of the device, that furnishes or purports to furnish information for use of the device contains adequate information for such use, including indications, effects, routes, methods, and frequency and duration of administration and any relevant hazards, contraindications, side effects, and precautions, under which practitioners licensed by law to employ the device can use the device safely and for the purposes for which it is intended, including all purposes for which it is advertised or represented. This 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. | (d) 该法案第 201(m) 节中定义的任何标签，无论它是否位于用于分配、由制造商、包装商或分销商或代表制造商、 包装商或分销商分发、分发的包装上或内部提供或声称提供设备使用信息的设备的信息包含此类使用的充分信息，包括 适应症、效果、途径、方法、给药频率和持续时间以及任何相关的危害、禁忌症、副作用和预防措施，根据该条款，获 得法律许可使用该设备的从业人员可以安全地使用该设备并用于其预期目的，包括宣传或代表该设备的所有目的。所谓 的提醒 - 件标签上不需要此信息，该标签会引起对设备名称的注意，但不包括指示或其他使用信息。 |
| (e) All labeling, except labels and cartons, bearing information for use of the device also bears the date of the issuance or the date of the latest revision of such labeling. | (e) 所有标签，除标签和纸箱外，带有设备使用信息的标签还带有发布日期或此类标签的最新修订日期。 |
| **§ 801.110 Retail exemption for prescription devices.** | **801.110 处方设备的零售豁免。** |
| A device subject to § 801.109 shall be exempt at the time of delivery to the ultimate purchaser or user from section 502(f)(1) of the act if it is delivered by a licensed practitioner in the course of his professional practice or upon a prescription or other order lawfully issued in the course of his professional practice, with labeling bearing the name and address of such licensed practitioner and the directions for use and cautionary statements, if any, contained in such order. | 受 § 801.109 约束的设备在交付给最终购买者或用户时，如果它是由有执照的从业者在其专业实践过程中交付或在在 其专业执业过程中合法签发的处方或其他命令，标签上应注明该执业医师的姓名和地址，以及该命令中包含的使用说明 和警告声明（如有）。 |
| **§ 801.116 Medical devices having commonly known directions.** | **801.116 具有普遍已知方向的医疗设备。** |
| A device shall be exempt from section 502(f)(1) of the act insofar as adequate directions for common uses thereof are known to the ordinary individual. | 只要普通个人知道其常用用途的适当说明，该设备应不受该法案第 502(f)(1) 条的约束。 |
| **§ 801.119 In vitro diagnostic products.** | **801.119 体外诊断产品。** |

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| A product intended for use in the diagnosis of disease and which is an in vitro diagnostic product as defined in § 809.3(a) of this chapter shall be deemed to be in compliance with the requirements of this part and section 502(f)(1) of the Federal Food, Drug, and Cosmetic Act if it meets the requirements of subpart B of this part and the requirements of § 809.10 of this chapter. | 用于疾病诊断的产品，如本章第 809.3(a) 节定义的体外诊断产品，应被视为符合本部分和第 502(f)(1) 节的要求) 的联邦食品、药品和化妆品法，如果它符合本部分 B 子部分的要求和本章第 809.10 节的要求。 |
| **§ 801.122 Medical devices for processing, repacking, or manufacturing.** | **801.122 用于加工、重新包装或制造的医疗器械。** |
| A device intended for processing, repacking, or use in the manufacture of another drug or device shall be exempt from section 502(f)(1) of the act if its label bears the statement "Caution: For manufacturing, processing, or repacking". | 用于加工、重新包装或用于制造另一种药物或器械的器械，如果其标签上标有"注意：用于制造、加工或重新包装"的声 明，则应免除该法案第 502(f)(1) 条的规定. |
| **§ 801.125 Medical devices for use in teaching, law enforcement, research, and analysis.** | **801.125 用于教学、执法、研究和分析的医疗器械。** |
| A device subject to § 801.109 shall be exempt from section 502(f)(1) of this act if shipped or sold to, or in the possession of, persons regularly and lawfully engaged in instruction in pharmacy, chemistry, or medicine not involving clinical use, or engaged in law enforcement, or in research not involving clinical use, or in chemical analysis, or physical testing, and is to be used only for such instruction, law enforcement, research, analysis, or testing. | 受 § 801.109 约束的设备如果被运送或出售给定期合法从事不涉及临床的药学、化学或医学教学的人员或由其拥有， 则应免除本法第 502(f)(1) 条的规定。使用，或从事执法，或不涉及临床使用的研究，或化学分析或物理测试，并且 仅用于此类指导、执法、研究、分析或测试。 |
| **§ 801.127 Medical devices; expiration of exemptions.** | **801.127 医疗器械；豁免期满。** |
| (a) If a shipment or delivery, or any part thereof, of a device which is exempt under the regulations in this section is made to a person in whose possession the article is not exempt, or is made for any purpose other than those specified, such exemption shall expire, with respect to such shipment or delivery or part thereof, at the beginning of that shipment or delivery. The causing of an exemption to expire shall be considered an act which results in such device being misbranded unless it is disposed of under circumstances in which it ceases to be a drug or device. | (a) 如果根据本条的规定被豁免的设备的装运或交付或其任何部分是由拥有该物品的人提供的，或者是出于指定目的以 外的任何目的, 就该装运或交付或其部分而言，该豁免应在该装运或交付开始时到期。导致豁免到期的行为应被视为导 致此类器械贴错标签的行为，除非在其不再是药物或器械的情况下对其进行处置。 |
| (b) The exemptions conferred by §§ 801.119, 801.122, and 801.125 shall continue until the devices are used for the purposes for which they are exempted, or until they are relabeled to comply with section 502(f)(1) of the act. If, however, the device is converted, or manufactured into a form limited to prescription dispensing, no exemption shall thereafter apply to the article unless the device is labeled as required by § 801.109. | (b) §§ 801.119、801.122 和 801.125 授予的豁免应持续到设备用于豁免目的，或重新贴上标签以符合法案第 502(f)(1) 节. 但是，如果设备被转换或制造成仅限于处方配药的形式，则此后不得豁免适用于该物品，除非该设备 按照 § 801.109 的要求贴上标签。 |
| **§ 801.128 Exceptions or alternatives to labeling requirements for medical devices held by the Strategic National Stockpile.** | **801.128 国家战略储备持有的医疗器械标签要求的例外或替代方案。** |
| (a) The appropriate FDA Center Director may grant an exception or alternative to any provision listed in paragraph (f) of this section and not explicitly required by statute, for specified lots, batches, or other units of a medical device, if the Center Director | (a) 适当的 FDA 中心主任可以对本节 (f) 段中列出的、法规未明确要求的医疗器械的指定批次、批次或其他单位授 予例外或替代，如果中 |

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| determines that compliance with such labeling requirement could adversely affect the safety, effectiveness, or availability of such devices that are or will be included in the Strategic National Stockpile. | 心主任确定，遵守此类标签要求可能会对已包含或将包含在国家战略库存中的此类设备的安全 性、有效性或可用性产生不利影响。 |
| (b) (1) (i) A Strategic National Stockpile official or any entity that manufactures (including labeling, packing, relabeling, or repackaging), distributes, or stores devices that are or will be included in the Strategic National Stockpile may submit, with written concurrence from a Strategic National Stockpile official, a written request for an exception or alternative described in paragraph (a) of this section to the Center Director. | (b)(1)(i) 国家战略储备官员或任何制造（包括贴标签、包装、重新贴标签或重新包装）、分销或存储已列入或将包括 在国家战略储备中的设备的实体可以提交，经国家战略储备官员书面同意，向中心主任提出本节 (a) 段中所述的例外或替代方案的书面请求。 |
| (ii) The Center Director may grant an exception or alternative described in paragraph (a) of this section on his or her own initiative. | (ii) 中心主任可主动授予本节 (a) 段所述的例外或替代方案。 |
| (2) A written request for an exception or alternative described in paragraph (a) of this section must: | (2) 本节 (a) 段中描述的例外或替代的书面请求必须： |
| (i) Identify the specified lots, batches, or other units of the medical device that would be subject to the exception or alternative; | (i) 识别可能受到例外或替代的医疗器械的指定批次、批次或其他单位； |
| (ii) Identify the labeling provision(s) listed in paragraph (f) of this section that are the subject of the exception or alternative request; | (ii) 确定本节 (f) 段中列出的属于例外或替代请求的标签规定； |
| (iii) Explain why compliance with the labeling provision(s) could adversely affect the safety, effectiveness, or availability of the specified lots, batches, or other units of a medical device that are or will be held in the Strategic National Stockpile; | (iii) 解释为什么遵守标签规定可能会对特定批次、批次或其他单位的医疗器械的安全性、有效性或可用性产生不利影 响，这些医疗器械将被或将被保存在国家战略库存中； |
| (iv) Describe any proposed safeguards or conditions that will be implemented so that the labeling of the device includes appropriate information necessary for the safe and effective use of the device, given the anticipated circumstances of use of the device; | (iv) 描述将实施的任何建议的保障措施或条件，以便在设备的预期使用情况下，设备的标签包括安全和有效使用设备 所需的适当信息； |
| (v) Provide a draft of the proposed labeling of the specified lots, batches, or other units of the medical device subject to the exception or alternative; and | (v) 提供医疗器械的指定批次、批次或其他单位的建议标签草案，但受例外或替代限制；和 |
| (vi) Provide any other information requested by the Center Director in support of the request. | (vi) 提供中心主任要求的任何其他信息以支持该请求。 |
| (c) The Center Director must respond in writing to all requests under this section. The Center Director may impose appropriate conditions when granting such an exception or alternative under this section. | (c) 中心主任必须以书面形式回应本节下的所有请求。在根据本节授予此类例外或替代方案时，中心主任可以施加适当 的条件。 |
| (d) A grant of an exception or alternative under this section will include any safeguards or conditions deemed appropriate by the Center Director so that the labeling of devices subject to the exception or alternative includes the information necessary for the safe and effective use of the device, given the anticipated circumstances of use. | (d) 根据本节授予的例外或替代方案将包括中心主任认为适当的任何保障措施或条件，以便受例外或替代方案约束的设 备的标签包括安全有效使用设备所需的信息，考虑到预期的使用情况。 |

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| (e) If the Center Director grants a request for an exception or alternative to the labeling requirements under this section: | (e) 如果中心主任根据本节批准标签要求的例外或替代请求： |
| (1) The Center Director may determine that the submission and grant of a written request under this section satisfies the provisions relating to premarket notification submissions under § 807.81(a)(3) of this chapter. | (1) 中心主任可以确定根据本节提交和批准书面请求是否符合本章第 807.81(a)(3) 条下有关上市前通知提交的规 定。 |
| (2) (i) For a Premarket Approval Application (PMA)-approved device, the submission and grant of a written request under this section satisfies the provisions relating to submission of PMA supplements under § 814.39 of this chapter; however, | (2) (i) 对于上市前批准申请 (PMA) 批准的器械，根据本节提交和批准书面请求符合本章第 814.39 节下有关提交 PMA 补充的规定；然而， |
| (ii) The grant of the request must be identified in a periodic report under § 814.84 of this chapter. | (ii) 根据本章第 814.84 节，必须在定期报告中确定批准请求。 |
| (f) The Center Director may grant an exception or alternative under this section to the following provisions of this chapter, to the extent that the requirements in these provisions are not explicitly required by statute: | (f) 中心主任可以根据本节对本章的以下规定给予例外或替代，只要这些规定中的要求没有被法规明确要求： |
| (1) § 801.1(d); | (1) § 801.1(d)； |
| (2) Subpart B of this part and part 830 of this chapter in its entirety; | (2) 本部分B分部和本章第830部分全文； |
| (3) § 801.60; | (3) § 801.60； |
| (4) § 801.61; | (4) § 801.61； |
| (5) § 801.62; | (5) § 801.62； |
| (6) § 801.63; | (6) § 801.63； |
| (7) § 801.109; and | (7) § 801.109；和 |
| (8) Part 801, subpart H. | (8) 第 801 部分，H 小节。 |
| Subpart E - Other Exemptions | E部分 - 其他豁免 |
| **§801.150 Medical devices;processing, labeling, or repacking** | **801.150 医疗器械；加工、贴标签或重新包装** |
| (a) Except as provided by paragraphs (b) and (c) of this section, a shipment or other delivery of a device which is, in accordance with the practice of the trade, to be processed, labeled, or repacked, in substantial quantity at an establishment other than that where originally processed or packed, shall be exempt, during the time of introduction into and movement in interstate commerce and the time of holding in such establishment, from compliance with the labeling and packaging requirements of section 502(b) and (f) of the act if: | (a) 除本节 (b) 和 (c) 段另有规定外，根据行业惯例，将要处理、贴标签或重新包装的大量设备的装运或其他交付 在非最初加工或包装的企业中的数量，在引入和进入州际贸易期间以及在该企业中持有期间，应免于遵守第 502(b) 节的标签和包装要求) 和 (f) 如果： |
| (1) The person who introduced such shipment or delivery into interstate commerce is the operator of the establishment where such device is to be processed, labeled, or repacked; or | (1) 将此类装运或交付引入州际贸易的人是要处理、标记或重新包装此类设备的场所的经营 |

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| | 者；或者 |
| (2) In case such person is not such operator, such shipment or delivery is made to such establishment under a written agreement, signed by and containing the post office addresses of such person and such operator, and containing such specifications for the processing, labeling, or repacking, as the case may be, of such device in such establishment as will insure, if such specifications are followed, that such device will not be adulterated or misbranded within the meaning of the act upon completion of such processing, labeling, or repacking. Such person and such operator shall each keep a copy of such agreement until 2 years after the final shipment or delivery of such device from such establishment, and shall make such copies available for inspection at any reasonable hour to any officer or employee of the Department who requests them. | (2) 如果该人不是该运营商，则该运输或交付是根据书面协议向该机构进行的，该协议由该人和该运营商签署并包含邮 局地址，并包含有关处理、标签的规范, 或重新包装此类设备（视情况而定），以确保，如果遵循此类规范，则在完成 此类处理、标签或重新包装。此类人员和此类操作员应各自保留此类协议的副本，直至从此类机构最终装运或交付此类 设备后 2 年，并应在任何合理时间将此类副本提供给部门的任何官员或雇员，要求他们。 |
| (b) An exemption of a shipment or other delivery of a device under paragraph (a)(1) of this section shall, at the beginning of the act of removing such shipment or delivery, or any part thereof, from such establishment, become void ab initio if the device comprising such shipment, delivery, or part is adulterated or misbranded within the meaning of the act when so removed. | (b) 根据本节 (a)(1) 款对设备的装运或其他交付的豁免应在将此类装运或交付或其任何部分从此类设施中移除的行 为开始时变为如果包含此类装运、交付或部件的设备在被移除后在该法案的含义内被掺假或贴错标签，则自始无效。 |
| (c) An exemption of a shipment or other delivery of a device under paragraph (a)(2) of this section shall become void ab initio with respect to the person who introduced such shipment or delivery into interstate commerce upon refusal by such person to make available for inspection a copy of the agreement, as required by such paragraph (a)(2). | (c) 根据本节 (a)(2) 款对设备的装运或以其他方式交付的豁免，对于将此类装运或交付引入州际贸易的人，在该人 拒绝的情况下自始无效。按照该(a)(2)段的要求，提供一份协议的副本以供查阅。 |
| (d) An exemption of a shipment or other delivery of a device under paragraph (a)(2) of this section shall expire: | (d) 根据本节 (a)(2) 款对设备的装运或其他交付的豁免应到期： |
| (1) At the beginning of the act of removing such shipment or delivery, or any part thereof, from such establishment if the device comprising such shipment, delivery, or part is adulterated or misbranded within the meaning of the act when so removed; or | (1) 在将此类货物或交付物或其任何部分从此类设施中移除的行为开始时，如果包含此类货物、交付物或部分的设备在 移除时的行为所指的范围内被掺假或贴错标签；或者 |
| (2) Upon refusal by the operator of the establishment where such device is to be processed, labeled, or repacked, to make available for inspection a copy of the agreement, as required by such clause. | (2) 在处理、标记或重新包装此类设备的企业的经营者拒绝按照该条款的要求提供协议副本以供检查时。 |
| (e) As it is a common industry practice to manufacture and/or assemble, package, and fully label a device as sterile at one establishment and then ship such device in interstate commerce to another establishment or to a contract sterilizer for sterilization, the Food and Drug Administration will initiate no regulatory action against the device as misbranded or adulterated when the nonsterile device is labeled sterile, provided all the following conditions are met: | (e) 由于在一个机构制造和/或组装、包装和完全标记器械无菌，然后在州际贸易中将此类器械运送到另一家机构或合 同灭菌器进行灭菌，这是一种常见的行业惯例，食品如果非无菌器械被标记为无菌，只要满足以下所有条件，药物管理 局将不会对该器械进行监管行动，因为该器械贴错标签或掺假： |
| (1) There is in effect a written agreement which: | (1) 存在有效的书面协议： |
| (i) Contains the names and post office addresses of the firms involved and is signed by the person authorizing such shipment | (i) 包含相关公司的名称和邮局地址，并由授权此类运输的人员和接收灭菌设备的企业的经营 |

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| and the operator or person in charge of the establishment receiving the devices for sterilization. | 者或负责人签名。 |
| (ii) Provides instructions for maintaining proper records or otherwise accounting for the number of units in each shipment to insure that the number of units shipped is the same as the number received and sterilized. | (ii) 提供有关维护适当记录或以其他方式计算每次装运中的单位数量的说明，以确保装运的单位数量与收到和消毒的 数量相同。 |
| (iii) Acknowledges that the device is nonsterile and is being shipped for further processing, and | (iii) 确认该设备是非无菌的并且正在运送以进行进一步处理，并且 |
| (iv) States in detail the sterilization process, the gaseous mixture or other media, the equipment, and the testing method or quality controls to be used by the contract sterilizer to assure that the device will be brought into full compliance with the Federal Food, Drug, and Cosmetic Act. | (iv) 详细说明灭菌过程、气体混合物或其他介质、设备以及合同灭菌器将使用的测试方法或质量控制，以确保设备完 全符合联邦食品，药品和化妆品法。 |
| (2) Each pallet, carton, or other designated unit is conspicuously marked to show its nonsterile nature when it is introduced into and is moving in interstate commerce, and while it is being held prior to sterilization. Following sterilization, and until such time as it is established that the device is sterile and can be released from quarantine, each pallet, carton, or other designated unit is conspicuously marked to show that it has not been released from quarantine, e.g., “sterilized - awaiting test results” or an equivalent designation. | (2) 每个托盘、纸箱或其他指定的单元在被引入和在州际贸易中移动时，以及在灭菌前被保存时，都被显着标记以显示 其非无菌性质。灭菌后，直到确定该设备是无菌的并且可以解除检疫时，每个托盘、纸箱或其他指定单元都显着标记以 表明它尚未解除检疫，例如“已灭菌” - 等待测试结果”或同等名称。 |
| **Subparts F-G [Reserved]** | **F-G部分 [保留]** |
| **Subpart H - Special Requirements for Specific Devices** | **H部分 - 特定设备的特殊要求** |
| **§ 801.405 Labeling of articles intended for lay use in the repairing and/or refitting of dentures.** | **801.405 用于修复和/或改装假牙的物品的标签。** |
| (a) The American Dental Association and leading dental authorities have advised the Food and Drug Administration of their concern regarding the safety of denture reliners, repair kits, pads, cushions, and other articles marketed and labeled for lay use in the repairing, refitting, or cushioning of ill-fitting, broken, or irritating dentures. It is the opinion of dental authorities and the Food and Drug Administration that to properly repair and properly refit dentures a person must have professional knowledge and specialized technical skill. Laymen cannot be expected to maintain the original vertical dimension of occlusion and the centric relation essential in the proper repairing or refitting of dentures. The continued wearing of improperly repaired or refitted dentures may cause acceleration of bone resorption, soft tissue hyperplasia, and other irreparable damage to the oral cavity. Such articles designed for lay use should be limited to emergency or temporary situations pending the services of a licensed dentist. | (a) 美国牙科协会和领先的牙科权威机构已向食品和药物管理局通报了他们对义齿衬垫、修复套件、垫、垫和其他销售 和标记用于修复、改装、或为不合适、破损或刺激性的假牙提供缓冲。牙科权威机构和食品药品监督管理局认为，要正 确修复和正确改装假牙，一个人必须具备专业知识和专业技术技能。不能指望外行人保持咬合的原始垂直尺寸和正确修 复或改装假牙所必需的中心关系。继续佩戴未正确修复或改装的假牙可能会导致骨吸收加速、软组织增生、以及对口腔 造成的其他无法弥补的损害。此类为非专业人士设计的物品应仅限于等待有执照的牙医服务的紧急或临时情况。 |
| (b) The Food and Drug Administration therefore regards such articles as unsafe and misbranded under the Federal Food, Drug, and Cosmetic Act, unless the labeling: | (b) 因此，根据《联邦食品、药品和化妆品法》，食品和药物管理局认为此类物品不安全且贴错标签，除非标签： |
| (1) (i) Limits directions for use for denture repair kits to | (1)(i) 将义齿修复套件的使用说明限制为紧急修 |

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| emergency repairing pending unavoidable delay in obtaining professional reconstruction of the denture; | 复，因为在获得义齿的专业重建过程中不可避免地出现延误； |
| (ii) Limits directions for use for denture reliners, pads, and cushions to temporary refitting pending unavoidable delay in obtaining professional reconstruction of the denture; | (ii) 将义齿衬垫、垫和垫子的使用说明限制为临时改装，因为在获得专业义齿重建过程中不可避免地延误； |
| (2) Contains in a conspicuous manner the word “emergency” preceding and modifying each indication for-use statement for denture repair kits and the word “temporary” preceding and modifying each indication-for-use statement for reliners, pads, and cushions; and | (2) 在义齿修复套件的每个使用说明之前和修改的每个使用说明之前以显着的方式包含“紧急”一词，在换衬套、垫和垫 的每个使用说明之前和修改的每个使用说明之前包含“临时”一词; 和 |
| (3) Includes a conspicuous warning statement to the effect: | (3) 包括一个明显的警告声明，大意是： |
| (i) For denture repair kits: “Warning - For emergency repairs only. Long term use of home-repaired dentures may cause faster bone loss, continuing irritation, sores, and tumors. This kit for emergency use only. See Dentist Without Delay.” | (i) 对于假牙修复工具包：“警告 - 仅用于紧急修复。 长期使用家庭修复的假牙可能会导致更快的骨质流失、持续的 刺激、溃疡和肿瘤。此工具包仅供紧急使用。请立即咨询牙医。 " |
| (ii) For denture reliners, pads, and cushions: “Warning - For temporary use only. Longterm use of this product may lead to faster bone loss, continuing irritation, sores, and tumors. For Use Only Until a Dentist Can Be Seen.” | (ii) 对于义齿修复垫、垫子和垫子：“警告 - 仅供临时使用。 长期使用本产品可能会导致更快的骨质流失、持续的刺 激、溃疡和肿瘤。仅在可以看到牙医之前使用。 " |
| (c) Adequate directions for use require full information of the temporary and emergency use recommended in order for the layman to understand the limitations of usefulness, the reasons therefor, and the importance of adhering to the warnings. Accordingly, the labeling should contain substantially the following information: | (c) 充分的使用说明需要有关建议的临时和紧急使用的完整信息，以便外行了解有用性的局限性、原因以及遵守警告的 重要性。因此，标签应包含以下信息： |
| (1) For denture repair kits: Special training and tools are needed to repair dentures to fit properly. Home repaired dentures may cause irritation to the gums and discomfort and tiredness while eating. Long term use may lead to more troubles, even permanent changes in bones, teeth, and gums, which may make it impossible to wear dentures in the future. For these reasons, dentures repaired with this kit should be used only in an emergency until a dentist can be seen. Dentures that don't fit properly cause irritation and injury to the gums and faster bone loss, which is permanent. Dentures that don't fit properly cause gum changes that may require surgery for correction. Continuing irritation and injury may lead to cancer in the mouth. You must see your dentist as soon as possible. | (1) 对于义齿修复工具包：需要特殊培训和工具来修复义齿以使其正确贴合。家庭修复的假牙可能会刺激牙龈以及进食 时的不适和疲倦。长期使用可能会导致更多的麻烦，甚至骨骼、牙齿和牙龈的永久性变化，这可能导致未来无法佩戴假 牙。由于这些原因，使用此套件修复的假牙应仅在紧急情况下使用，直到可以看到牙医。不合适的假牙会对牙龈造成刺 激和伤害，并且会加速骨质流失，这是永久性的。不合适的假牙会导致牙龈变化，可能需要手术矫正。持续的刺激和伤 害可能导致口腔癌。您必须尽快去看牙医。 |
| (2) For denture reliners, pads, and cushions: Use of these preparations or devices may temporarily decrease the discomfort; however, their use will not make the denture fit properly. Special training and tools are needed to repair a denture to fit properly. Dentures that do not fit properly cause irritation and injury to the gums and faster bone loss, which is permanent and may require a completely new denture. Changes in the gums caused by dentures that do not fit properly may require surgery for correction. Continuing irritation and injury | (2) 义齿修复垫、垫子和垫子：使用这些制剂或装置可能会暂时减轻不适感；但是，它们的使用不会使假牙正确贴合。 需要特殊培训和工具来修复假牙以使其正确贴合。不合适的假牙会对牙龈造成刺激和伤害，并导致更快的骨质流失，这 是永久性的，可能需要全新的假牙。由不合适的假牙引起的牙龈变化可能需要手术矫正。持续的刺激和伤害可能导致口 腔癌。您必 |

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| may lead to cancer in the mouth. You must see your dentist as soon as possible. | 须尽快去看牙医。 |
| (3) If the denture relining or repairing material forms a permanent bond with the denture, a warning statement to the following effect should be included: “This reliner becomes fixed to the denture and a completely new denture may be required because of its use.” | (3) 如果义齿重衬或修复材料与义齿形成永久结合，则应包括如下警告声明：“该重衬已固定在义齿上，可能需要使用 全新的义齿。 " |
| (d) Labeling claims exaggerating the usefulness or the safety of the material or failing to disclose all facts relevant to the claims of usefulness will be regarded as false and misleading under sections 201(n) and 502(a) of the Federal Food, Drug, and Cosmetic Act. | (d) 根据《联邦食品、药品》第 201(n) 和 502(a) 条，在标签上夸大材料的有用性或安全性或未披露与有用性声明 相关的所有事实将被视为虚假和误导和化妆品法。 |
| (e) Regulatory action may be initiated with respect to any article found within the jurisdiction of the act contrary to the provisions of this policy statement after 90 days following the date of publication of this section in the FEDERAL REGISTER. | (e) 自本节在联邦公报上公布之日起 90 天后，可对在该法案管辖范围内发现的违反本政策声明规定的任何物品采取监 管行动。 |
| **§ 801.410 Use of impact-resistant lenses in eyeglasses and sunglasses.** | **801.410 在眼镜和太阳镜中使用抗冲击镜片。** |
| (a) Examination of data available on the frequency of eye injuries resulting from the shattering of ordinary crown glass lenses indicates that the use of such lenses constitutes an avoidable hazard to the eye of the wearer. | (a) 对普通冠状玻璃镜片破碎导致眼部受伤频率的现有数据的审查表明，使用此类镜片对佩戴者的眼睛构成可避免的危 害。 |
| (b) The consensus of the ophthalmic community is that the number of eye injuries would be substantially reduced by the use in eyeglasses and sunglasses of impact-resistant lenses. | (b) 眼科界的共识是，在眼镜和太阳镜中使用抗冲击镜片会大大减少眼部受伤的次数。 |
| (c) (1) To protect the public more adequately from potential eye injury, eyeglasses and sunglasses must be fitted with impact-resistant lenses, except in those cases where the physician or optometrist finds that such lenses will not fulfill the visual requirements of the particular patient, directs in writing the use of other lenses, and gives written notification thereof to the patient. | (c)(1) 为了更充分地保护公众免受潜在的眼部伤害，眼镜和太阳镜必须配备抗冲击镜片，除非医生或验光师发现此类 镜片不能满足视觉要求特定患者，以书面形式指示使用其他镜片，并向患者提供书面通知。 |
| (2) The physician or optometrist shall have the option of ordering glass lenses, plastic lenses, or laminated glass lenses made impact resistant by any method; however, all such lenses shall be capable of withstanding the impact test described in paragraph (d)(2) of this section. | (2) 医师或验光师可以选择订购玻璃镜片、塑料镜片或通过任何方法制成抗冲击的夹层玻璃镜片；但是，所有此类镜片 都应能够承受本节 (d)(2) 段所述的冲击试验。 |
| (3) Each finished impact-resistant glass lens for prescription use shall be individually tested for impact resistance and shall be capable of withstanding the impact test described in paragraph (d)(2) of this section. Raised multifocal lenses shall be impact resistant but need not be tested beyond initial design testing. Prism segment multifocal, slab-off prism, lenticular cataract, iseikonic, depressed segment one-piece multifocal, bioconcave, myodisc and minus lenticular, custom laminate and cemented assembly lenses shall be impact resistant but need not be subjected to impact testing. To demonstrate that all other types of impact-resistant lenses, including impact-resistant laminated glass lenses (i.e., lenses other than those described in the three preceding sentences of this paragraph (c)(3)), are capable of withstanding the impact test described in this regulation, the | (3) 每个成品抗冲击玻璃镜片应单独进行抗冲击测试，并应能够承受本节 (d)(2) 段所述的冲击测试。凸起的多焦点 镜片应具有抗冲击性，但在初始设计测试之后无需进行测试。棱镜段多焦点、平板棱镜、透镜状白内障、等康透镜、凹 陷段一体式多焦点、生物凹、肌盘和负透镜、定制层压和胶合组装镜片应具有抗冲击性，但无需进行冲击测试。证明所 有其他类型的抗冲击镜片，包括抗冲击夹层玻璃镜片（即除本段 (c)(3) 前三句中描述的镜片），能够承受本法规中描 述的冲击测试，这些镜片的制造商应接受冲击测试，从每个生产批次中抽取具 |

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| manufacturer of these lenses shall subject to an impact test a statistically significant sampling of lenses from each production batch, and the lenses so tested shall be representative of the finished forms as worn by the wearer, including finished forms that are of minimal lens thickness and have been subjected to any treatment used to impart impact resistance. All nonprescription lenses and plastic prescription lenses tested on the basis of statistical significance shall be tested in uncut finished or finished form. | 有统计意义的镜片样本，并且如此测试的 镜片应代表佩戴者佩戴的成品形式佩戴者，包括镜片厚度最小的成品镜片，并经过任何用于赋予抗冲击性的处理。根据统计显着性测试的所有非处方镜片和塑料处方镜片应以未切割或成品形式进行测试。并且如此测试的镜片应代表佩戴者 佩戴的成品形式，包括具有最小镜片厚度并经过任何用于赋予抗冲击性的处理的成品形式。根据统计显着性测试的所有 非处方镜片和塑料处方镜片应以未切割或成品形式进行测试。并且如此测试的镜片应代表佩戴者佩戴的成品形式，包括 具有最小镜片厚度并经过任何用于赋予抗冲击性的处理的成品形式。根据统计显着性测试的所有非处方镜片和塑料处方 镜片应以未切割或成品形式进行测试。 |
| (d) (1) For the purpose of this regulation, the impact test described in paragraph (d)(2) of this section shall be the “referee test,” defined as “one which will be utilized to determine compliance with a regulation.” The referee test provides the Food and Drug Administration with the means of examining a medical device for performance and does not inhibit the manufacturer from using equal or superior test methods. A lens manufacturer shall conduct tests of lenses using the impact test described in paragraph (d)(2) of this section or any equal or superior test. Whatever test is used, the lenses shall be capable of withstanding the impact test described in paragraph (d)(2) of this section if the Food and Drug Administration examines them for performance. | (d)(1) 就本条例而言，本节 (d)(2) 段所述的冲击试验应为“裁判试验”，其定义为“用于确定是否符合规定的试验” 。” 裁判测试为食品和药物管理局提供了检查医疗器械性能的方法，并且不会阻止制造商使用同等或优越的测试方法。 镜片制造商应使用本节 (d)(2) 中所述的冲击试验或任何同等或更高的试验对镜片进行试验。无论使用何种测试，如果 食品和药物管理局对其性能进行检查，镜片应能够承受本节 (d)(2) 段所述的冲击测试。 |
| (2) In the impact test, a 5 ⁄8-inch steel ball weighing approximately 0.56 ounce is dropped from a height of 50 inches upon the horizontal upper surface of the lens. The ball shall strike within a 5⁄8-inch diameter circle located at the geometric center of the lens. The ball may be guided but not restricted in its fall by being dropped through a tube extending to within approximately 4 inches of the lens. To pass the test, the lens must not fracture; for the purpose of this section, a lens will be considered to have fractured if it cracks through its entire thickness, including a laminar layer, if any, and across a complete diameter into two or more separate pieces, or if any lens material visible to the naked eyes becomes detached from the ocular surface. The test shall be conducted with the lens supported by a tube (1-inch inside diameter, 11⁄4-inch outside diameter, and approximately 1-inch high) affixed to a rigid iron or steel base plate. The total weight of the base plate and its rigidly attached fixtures shall be not less than 27 pounds. For lenses of small minimum diameter, a support tube having an outside diameter of less than 11⁄4 inches may be used. The support tube shall be made of rigid acrylic plastic, steel, or other suitable substance and shall have securely bonded on the top edge a 1⁄8- by 1⁄8-inch neoprene gasket having a hardness of 40 ±5, as determined by ASTM Method D 1415-88, “Standard Test Method for Rubber Property - International Hardness” a minimum tensile strength of 1,200 pounds, as determined by | (2) 在冲击试验中，将一个重约 0.56 盎司的 5/8 英寸钢球从 50 英寸的高度落到镜片的水平上表面上。球应在位 于镜片几何中心的直径为 5/8 英寸的圆内撞击。球可以通过延伸到距镜片约 4 英寸范围内的管子下落来引导，但不限 制其下落。为通过测试，镜片不得断裂；就本节而言，如果镜片在其整个厚度上破裂，包括层状层（如果有的话），并 在整个直径上裂成两个或多个单独的碎片，或者如果任何镜片材料可见肉眼与眼表分离。测试应在由管子支撑的镜头 （内径 1 英寸，外径 1 1/4 英寸，高约 1 英寸）固定在刚性铁或钢底板上。底板及其刚性连接的固定装置的总重量 应不小于 27 磅。对于最小直径小的镜片，可以使用外径小于 1 1/4 英寸的支撑管。支撑管应由硬质丙烯酸塑料、钢 或其他合适的材料制成，并应在顶部边缘牢固地粘合一个 1/8 x 1/8 英寸的氯丁橡胶垫圈，其硬度为 40 +/-5，如 由 ASTM 方法 D 1415-88，“橡胶性能的标准测试方法 - 国际硬度”确定最小拉伸强度为 1,200 磅，由 ASTM 方 法 D 412-98A，“硫化橡胶和热塑性弹性体的标准测试方法 - 张力”确定" 或可在设备和放射健康中心 |

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| ASTM Method D 412-98A, “Standard Test Methods for Vulcanized Rubber and Thermoplastic Elastomers - Tension,” and a minimum ultimate elongation of 400 percent, as determined by ASTM Method D 412-68 (Both methods are incorporated by reference and are available from the American Society for Testing Materials, 100 Barr Harbor Dr., West Conshohocken, Philadelphia, PA 19428, or available for inspection at the Center for Devices and Radiological Health's Library, 9200 Corporate Blvd., Rockville, MD 20850, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ ibr_locations.html. The diameter or contour of the lens support may be modified as necessary so that the 1⁄8- by 1⁄8-inch neoprene gasket supports the lens at its periphery. | 图书馆（地址为 9200 Corporate Blvd., Rockville, MD 20850）或国家档案和记录管理局 (NARA) 查阅。有关在 NARA 获取此 材料的信息，请致电 202-741-6030，或访问：或可在设备和放射健康中心图书馆（地址为 9200 Corporate Blvd., Rockville, MD 20850）或国家档案和记录管理局 (NARA) 查阅。有关在 NARA 获取此材料的信息，请致 电 202-741-6030，或访问：http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html。 可以根据需要修改镜片支架的直径或轮廓，以便 1/8 x 1/8 英寸的氯丁橡胶垫圈在其周边支撑镜片。 |
| (e) Copies of invoice(s), shipping document(s), and records of sale or distribution of all impact resistant lenses, including finished eyeglasses and sunglasses, shall be kept and maintained for a period of 3 years; however, the names and addresses of individuals purchasing nonprescription eyeglasses and sunglasses at the retail level need not be kept and maintained by the retailer. The records kept in compliance with this paragraph shall be made available upon request at all reasonable hours by any officer or employee of the Food and Drug Administration or by any other officer or employee acting on behalf of the Secretary of Health and Human Services and such officer or employee shall be permitted to inspect and copy such records, to make such inventories of stock as he deems necessary, and otherwise to check the correctness of such inventories. | (e) 所有抗冲击镜片（包括成品眼镜和太阳镜）的发票、运输文件和销售或分销记录的副本应保存 3 年；但是，在零 售层面购买非处方眼镜和太阳镜的个人的姓名和地址无需由零售商保存和维护。根据本款保存的记录应由食品和药物管 理局的任何官员或雇员或代表卫生与公众服务部部长和该官员行事的任何其他官员或雇员在所有合理时间提供或员工应 被允许检查和复制这些记录，制作他认为必要的库存盘点，以及检查这些盘点的正确性。 |
| (f) In addition, those persons conducting tests in accordance with paragraph (d) of this section shall maintain the results thereof and a description of the test method and of the test apparatus for a period of 3 years. These records shall be made available upon request at any reasonable hour by any officer or employee acting on behalf of the Secretary of Health and Human Services. The persons conducting tests shall permit the officer or employee to inspect and copy the records, to make such inventories of stock as the officer or employee deems necessary, and otherwise to check the correctness of the inventories | (f) 此外，按照本条 (d) 款进行测试的人员应将测试结果以及测试方法和测试设备的说明保存 3 年。这些记录应由 代表卫生与公众服务部部长的任何官员或雇员在任何合理时间应要求提供。进行测试的人员应允许管理人员或雇员检查 和复制记录，制作高级人员或雇员认为必要的库存清单，以及检查清单的正确性。 |
| (g) For the purpose of this section, the term “manufacturer” includes an importer for resale. Such importer may have the tests required by paragraph (d) of this section conducted in the country of origin but must make the results thereof available, upon request, to the Food and Drug Administration, as soon as practicable. | (g) 为本节的目的，“制造商”一词包括转售进口商。此类进口商可以在原产国进行本节 (d) 段要求的测试，但必须根 据要求尽快将结果提供给食品和药物管理局。 |
| (h) All lenses must be impact-resistant except when the physician or optometrist finds that impact-resistant lenses will not fulfill the visual requirements for a particular patient. | (h) 所有镜片都必须是耐冲击的，除非医生或验光师发现耐冲击镜片不能满足特定患者的视觉要求。 |

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| (i) This statement of policy does not apply to contact lenses. | (i) 本政策声明不适用于隐形眼镜。 |
| **§ 801.415 Maximum acceptable level of ozone.** | **801.415 最高可接受的臭氧水平。** |
| (a) Ozone is a toxic gas with no known useful medical application in specific, adjunctive, or preventive therapy. In order for ozone to be effective as a germicide, it must be present in a concentration far greater than that which can be safely tolerated by man and animals. | (a) 臭氧是一种有毒气体，在特定、辅助或预防性治疗中没有已知的有用医学用途。为了使臭氧作为杀菌剂有效，它的 浓度必须远高于人和动物可以安全耐受的浓度。 |
| (b) Although undesirable physiological effects on the central nervous system, heart, and vision have been reported, the predominant physiological effect of ozone is primary irritation of the mucous membranes. Inhalation of ozone can cause sufficient irritation to the lungs to result in pulmonary edema. The onset of pulmonary edema is usually delayed for some hours after exposure; thus, symptomatic response is not a reliable warning of exposure to toxic concentrations of ozone. Since olfactory fatigue develops readily, the odor of ozone is not a reliable index of atmospheric ozone concentration. | (b) 尽管已经报道了对中枢神经系统、心脏和视力的不良生理影响，但臭氧的主要生理影响是对粘膜的主要刺激。吸入 臭氧会对肺部造成足够的刺激，从而导致肺水肿。肺水肿的发作通常在暴露后延迟数小时；因此，症状反应并不是暴露 于有毒浓度臭氧的可靠警告。由于嗅觉疲劳很容易发生，臭氧的气味并不是大气臭氧浓度的可靠指标。 |
| (c) A number of devices currently on the market generate ozone by design or as a byproduct. Since exposure to ozone above a certain concentration can be injurious to health, any such device will be considered adulterated and/or misbranded within the meaning of sections 501 and 502 of the act if it is used or intended for use under the following conditions: | (c) 目前市场上的一些设备通过设计或作为副产品产生臭氧。由于暴露于高于一定浓度的臭氧可能对健康有害，因此如 果在以下条件下使用或打算使用任何此类设备，则将被视为该法案第 501 和 502 节含义内的掺假和/或贴错标签： |
| (1) In such a manner that it generates ozone at a level in excess of 0.05 part per million by volume of air circulating through the device or causes an accumulation of ozone in excess of 0.05 part per million by volume of air (when measured under standard conditions at 25 °C (77 °F) and 760 millimeters of mercury) in the atmosphere of enclosed space intended to be occupied by people for extended periods of time, e.g., houses, apartments, hospitals, and offices. This applies to any such device, whether portable or permanent or part of any system, which generates ozone by design or as an inadvertent or incidental product. | (1) 以这样一种方式，它产生的臭氧水平超过百万分之 0.05（按空气循环通过设备的体积计）或导致臭氧积累超过百 万分之 0.05（按空气体积计）（当在以下条件下测量时）在 25 摄氏度（77 华氏度）和 760 毫米汞柱的标准条件下，在打算供人们长时间居住的封闭空间（例如房屋、公寓、医院和办公室）的大气中。这适用于任何此类设备，无论 是便携式设备还是永久性设备或任何系统的一部分，这些设备通过设计或作为无意或偶然的产品产生臭氧。 |
| (2) To generate ozone and release it into the atmosphere in hospitals or other establishments occupied by the ill or infirm. | (2) 在医院或其他病人或体弱者居住的场所产生臭氧并将其释放到大气中。 |
| (3) To generate ozone and release it into the atmosphere and does not indicate in its labeling the maximum acceptable concentration of ozone which may be generated (not to exceed 0.05 part per million by volume of air circulating through the device) as established herein and the smallest area in which such device can be used so as not to produce an ozone accumulation in excess of 0.05 part per million. | (3) 产生臭氧并将其释放到大气中，并且未在其标签中注明可能产生的最大可接受臭氧浓度（按通过设备循环的空气体 积计算，不超过百万分之 0.05），可以使用此类设备的最小区域，以免产生超过百万分之 0.05 的臭氧积累。 |
| (4) In any medical condition for which there is no proof of safety and effectiveness. | (4) 在没有安全性和有效性证明的任何医疗状况下。 |
| (5) To generate ozone at a level less than 0.05 part per million by volume of air circulating through the device and it is labeled | (5) 以通过设备循环的空气体积产生低于百万分之 0.05 的臭氧，并标记为用作杀菌剂或除臭 |

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| for use as a germicide or deodorizer. | 剂。 |
| (d) This section does not affect the present threshold limit value of 0.10 part per million (0.2 milligram per cubic meter) of ozone exposure for an 8-hour-day exposure of industrial workers as recommended by the American Conference of Governmental Industrial Hygienists. | (d) 本节不影响美国政府工业卫生学家会议建议的工业工人每天 8 小时接触臭氧的当前阈值限值，即百万分之 0.10 （每立方米 0.2 毫克）。 |
| (e) The method and apparatus specified in 40 CFR part 50, or any other equally sensitive and accurate method, may be employed in measuring ozone pursuant to this section. | (e) 40 CFR 第 50 部分中规定的方法和设备，或任何其他同样灵敏和准确的方法，可用于根据本节测量臭氧。 |
| **§ 801.417 Chlorofluorocarbon propellants.** | **801.417 氯氟烃推进剂。** |
| The use of chlorofluorocarbon in devices as propellants in self-pressurized containers is generally prohibited except as provided in § 2.125 of this chapter. | 除非本章第 2.125 节另有规定，否则一般禁止在装置中使用氯氟烃作为自压容器中的推进剂。 |
| **§ 801.420 Hearing aid devices; professional and patient labeling.** | **801.420 助听器；专业和患者标签。** |
| (a) Definitions for the purposes of this section and § 801.421. | (a)为本节和 § 801.421 目的的定义。 |
| (1) Hearing aid means any wearable instrument or device designed for, offered for the purpose of, or represented as aiding persons with or compensating for, impaired hearing. | (1)助听器 是指为听力受损的人设计、提供或代表为帮助或补偿听力受损的 人的任何可穿戴仪器或设备。 |
| (2) Ear specialist means any licensed physician who specializes in diseases of the ear and is medically trained to identify the symptoms of deafness in the context of the total health of the patient, and is qualified by special training to diagnose and treat hearing loss. Such physicians are also known as otolaryngologists, otologists, and otorhinolaryngologists. | (2)耳专科医生 是指任何执业医师，专攻耳部疾病，并接受过医学培训，能够在患者整体健康范围内识别耳聋症状，并 通过特殊培训有资格诊断和治疗听力损失。这样的医生也被称为耳鼻喉科医生、耳科医生和耳鼻喉科医生。 |
| (3) Dispenser means any person, partnership, corporation, or association engaged in the sale, lease, or rental of hearing aids to any member of the consuming public or any employee, agent, sales person, and/or representative of such a person, partnership, corporation, or association. | (3)配药商 是指从事向任何消费公众成员或任何雇员、代理人、销售人员和/或此类人的代表出售、租赁或出租助听器 的任何个人、合伙企业、公司或协会、合伙企业、公司或协会。 |
| (4) Audiologist means any person qualified by training and experience to specialize in the evaluation and rehabilitation of individuals whose communication disorders center in whole or in part in the hearing function. In some states audiologists must satisfy specific requirements for licensure. | (4)听力学家 是指通过培训和经验有资格专门评估和康复其沟通障碍全部或部分以听力功能为中心的个人的任何人。在 某些州，听力学家必须满足执照的特定要求。 |
| (5) Sale or purchase includes any lease or rental of a hearing aid to a member of the consuming public who is a user or prospective user of a hearing aid. | (5)销售 或购买 包括向作为助听器用户或潜在用户的消费公众成员出租或出租助听器。 |
| (6) Used hearing aid means any hearing aid that has been worn for any period of time by a user. However, a hearing aid shall not be considered “used” merely because it has been worn by a prospective user as a part of a bona fide hearing aid evaluation conducted to determine whether to select that particular hearing aid for that prospective user, if such evaluation has been conducted in the presence of the dispenser or a hearing aid health professional selected by the dispenser to assist the buyer | (6)使用过的助听器 是指用户佩戴任何时间的任何助听器。然而，助听器不应仅仅因为它已被潜在用户佩戴作为真正的 助听器评估的一部分而被视为“使用”，以确定是否为该潜在用户选择该特定助听器，如果此类评估已在分配器或分配器 选择的助听器健康专家在场的情况下进 |

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| in making such a determination. | 行，以协助购买者做出此类决定。 |
| (b) Label requirements for hearing aids. Hearing aids shall be clearly and permanently marked with: | (b)助听器的标签要求。 助听器应清楚且永久地标明： |
| (1) The name of the manufacturer or distributor, the model name or number, the serial number, and the year of manufacture. | (1) 制造商或经销商的名称、型号名称或编号、序列号、制造年份。 |
| (2) A “ + ” symbol to indicate the positive connection for battery insertion, unless it is physically impossible to insert the battery in the reversed position. | (2) “+”符号表示电池插入的正极连接，除非在物理上不可能将电池插入反向位置。 |
| (c) Labeling requirements for hearing aids -(1) General. All labeling information required by this paragraph shall be included in a User Instructional Brochure that shall be developed by the manufacturer or distributor, shall accompany the hearing aid, and shall be provided to the prospective user by the dispenser of the hearing aid in accordance with § 801.421(c). The User Instructional Brochure accompanying each hearing aid shall contain the following information and instructions for use, to the extent applicable to the particular requirements and characteristics of the hearing aid: | (c)助听器的标签要求 - (1)概述。 本段要求的所有标签信息均应包含在用户指导手册中，该手册应由制造商或分销商 开发，应随助听器一起提供，并应由助听器分配器根据§ 801.421(c)。每个助听器随附的用户说明手册应包含以下信息和使用说明，以适用于助听器的特定要求和特性： |
| (i) An illustration(s) of the hearing aid, indicating operating controls, user adjustments, and battery compartment. | (i) 助听器的插图，指示操作控制、用户调整和电池盒。 |
| (ii) Information on the function of all controls intended for user adjustment. | (ii) 有关供用户调整的所有控件的功能的信息。 |
| (iii) A description of any accessory that may accompany the hearing aid, e.g., accessories for use with a television or telephone. | (iii) 对可能伴随助听器的任何附件的描述，例如与电视或电话一起使用的附件。 |
| (iv) Specific instructions for: | (iv) 具体说明： |
| (a) Use of the hearing aid. | (a) 助听器的使用。 |
| (b) Maintenance and care of the hearing aid, including the procedure to follow in washing the earmold, when replacing tubing on those hearing aids that use tubing, and in storing the hearing aid when it will not be used for an extended period of time. | (b) 助听器的维护和保养，包括清洗耳模、更换使用管子的助听器上的管子以及长时间不使用助听器时的存放程序. |
| (c) Replacing or recharging the batteries, including a generic designation of replacement batteries. | (c) 更换或充电电池，包括更换电池的通用名称。 |
| (v) Information on how and where to obtain repair service, including at least one specific address where the user can go, or send the hearing aid to, to obtain such repair service. | (v) 有关如何以及在何处获得维修服务的信息，包括至少一个用户可以前往或将助听器寄往以获得此类维修服务的具体 地址。 |
| (vi) A description of commonly occurring avoidable conditions that could adversely affect or damage the hearing aid, such as dropping, immersing, or exposing the hearing aid to excessive heat. | (vi) 对可能对助听器产生不利影响或损坏的常见可避免情况的描述，例如坠落、浸入或将助听器暴露在过热的环境 中。 |
| (vii) Identification of any known side effects associated with the use of a hearing aid that may warrant consultation with a physician, e.g., skin irritation and accelerated accumulation of | (vii) 识别与使用助听器相关的任何已知副作用，可能需要咨询医生，例如皮肤刺激和耵聍 |

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| cerumen (ear wax). | （耳垢）加速积聚。 |
| (viii) A statement that a hearing aid will not restore normal hearing and will not prevent or improve a hearing impairment resulting from organic conditions. | (viii) 助听器不会恢复正常听力，也不会预防或改善由器质性疾病导致的听力损伤的声明。 |
| (ix) A statement that in most cases infrequent use of a hearing aid does not permit a user to attain full benefit from it. | (ix) 声明在大多数情况下不经常使用助听器不会让用户从中获得全部好处。 |
| (x) A statement that the use of a hearing aid is only part of hearing habilitation and may need to be supplemented by auditory training and instruction in lipreading. | (x) 声明使用助听器只是听力康复的一部分，可能需要辅以听觉训练和唇读指导。 |
| (xi) The warning statement required by paragraph (c)(2) of this section. | (xi) 本节 (c)(2) 段要求的警告声明。 |
| (xii) The notice for prospective hearing aid users required by paragraph (c)(3) of this section. | (xii) 本节 (c)(3) 段要求的潜在助听器用户通知。 |
| (xiii) The technical data required by paragraph (c)(4) of this section, unless such data is provided in separate labeling accompanying the device. | (xiii) 本节 (c)(4) 段要求的技术数据，除非这些数据在设备随附的单独标签中提供。 |
| (2) Warning statement. The User Instructional Brochure shall contain the following warning statement: | (2)警告声明。 用户指导手册应包含以下警告声明： |
| Warning to Hearing Aid Dispensers<br>A hearing aid dispenser should advise a prospective hearing aid user to consult promptly with a licensed physician (preferably an ear specialist) before dispensing a hearing aid if the hearing aid dispenser determines through inquiry, actual observation, or review of any other available information concerning the prospective user, that the prospective user has any of the following conditions: | 对助听器分配器的警告<br>如果助听器配药师通过询问、实际观察或审查任何其他有关助听器的可用信息确定，助听器配药师应建议准助听器用户 在配发助听器之前立即咨询有执照的医生（最好是耳科专家）。准用户，即准用户具有以下任一条件： |
| (i) Visible congenital or traumatic deformity of the ear | (i) 可见的耳朵先天性或外伤性畸形。 |
| (ii) History of active drainage from the ear within the previous 90 days. | (ii) 过去 90 天内从耳朵主动引流的历史。 |
| (iii) History of sudden or rapidly progressive hearing loss within the previous 90 days. | (iii) 过去 90 天内突发性或快速进行性听力损失的病史。 |
| (iv) Acute or chronic dizziness. | (iv) 急性或慢性头晕。 |
| (v) Unilateral hearing loss of sudden or recent onset within the previous 90 days. | (v) 在过去 90 天内突然或近期发作的单侧听力损失。 |
| (vi) Audiometric air-bone gap equal to or greater than 15 decibels at 500 hertz (Hz), 1,000 Hz, and 2,000 Hz. | (vi) 在 500 赫兹 (Hz)、1,000 赫兹和 2,000 赫兹时，测听气骨间隙等于或大于 15 分贝。 |
| (vii) Visible evidence of significant cerumen accumulation or a foreign body in the ear canal. | (vii) 耳道中有明显的耵聍堆积或异物的明显证据。 |
| (viii) Pain or discomfort in the ear | (viii) 耳朵疼痛或不适。 |
| Special care should be exercised in selecting and fitting a hearing aid whose maximum sound pressure level exceeds 132 | 在选择和安装最大声压级超过 132 分贝的助听 |

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| decibels because there may be risk of impairing the remaining hearing of the hearing aid user. (This provision is required only for those hearing aids with a maximum sound pressure capability greater than 132 decibels (dB).) | 器时应特别小心，因为可能存在损害助听器用户剩余听力的风险。（此 规定仅适用于最大声压能力大于 132 分贝 (dB) 的助听器。） |
| (3) Notice for prospective hearing aid users. The User Instructional Brochure shall contain the following notice: | (3)准助听器使用者须知。 用户指导手册应包含以下通知： |
| Important Notice for Prospective Hearing Aid Users | 给准助听器使用者的重要通知 |
| Good health practice requires that a person with a hearing loss have a medical evaluation by a licensed physician (preferably a physician who specializes in diseases of the ear) before purchasing a hearing aid. Licensed physicians who specialize in diseases of the ear are often referred to as otolaryngologists, otologists or otorhinolaryngologists. The purpose of medical evaluation is to assure that all medically treatable conditions that may affect hearing are identified and treated before the hearing aid is purchased. | 良好的健康习惯要求听力损失的人在购买助听器之前由有执照的医生（最好是专门研究耳部疾病的医生）进行医学评 估。专门研究耳部疾病的有执照的医生通常被称为耳鼻喉科医生、耳科医生或耳鼻喉科医生。医学评估的目的是确保在 购买助听器之前识别和治疗所有可能影响听力的医学上可治疗的疾病。 |
| Following the medical evaluation, the physician will give you a written statement that states that your hearing loss has been medically evaluated and that you may be considered a candidate for a hearing aid. The physician will refer you to an audiologist or a hearing aid dispenser, as appropriate, for a hearing aid evaluation. | 在进行医学评估后，医生会给您一份书面声明，说明您的听力损失已经过医学评估，并且您可能被认为是助听器的候选 人。医生会酌情将您转介给听力学家或助听器配药师进行助听器评估。 |
| The audiologist or hearing aid dispenser will conduct a hearing aid evaluation to assess your ability to hear with and without a hearing aid. The hearing aid evaluation will enable the audiologist or dispenser to select and fit a hearing aid to your individual needs. | 听力学家或助听器配发师将进行助听器评估，以评估您在使用和不使用助听器的情况下的听力能力。助听器评估将使听 力学家或配药师能够根据您的个人需求选择和安装助听器。 |
| If you have reservations about your ability to adapt to amplification, you should inquire about the availability of a trial-rental or purchase-option program. Many hearing aid dispensers now offer programs that permit you to wear a hearing aid for a period of time for a nominal fee after which you may decide if you want to purchase the hearing aid. | 如果您对自己适应放大的能力有所保留，您应该询问是否有试用租赁或购买选项计划。许多助听器配售商现在提供的程 序允许您以象征性的费用佩戴助听器一段时间，之后您可以决定是否要购买助听器。 |
| Federal law restricts the sale of hearing aids to those individuals who have obtained a medical evaluation from a licensed physician. Federal law permits a fully informed adult to sign a waiver statement declining the medical evaluation for religious or personal beliefs that preclude consultation with a physician. The exercise of such a waiver is not in your best health interest and its use is strongly discouraged. | 联邦法律限制将助听器销售给那些从有执照的医生那里获得医学评估的个人。联邦法律允许完全知情的成年人签署一份 弃权声明，拒绝对排除与医生咨询的宗教或个人信仰进行医学评估。行使此类豁免不符合您的最佳健康利益，强烈建议 不要使用。 |
| children with hearing loss | 听力损失儿童 |
| In addition to seeing a physician for a medical evaluation, a child with a hearing loss should be directed to an audiologist for evaluation and rehabilitation since hearing loss may cause problems in language development and the educational and social growth of a child. An audiologist is qualified by training and experience to assist in the evaluation and rehabilitation of a child with a hearing loss. | 除了去看医生进行医学评估外，听力损失的孩子还应该被引导到听力学家那里进行评估和康复，因为听力损失可能会导 致孩子的语言发展以及教育和社会成长出现问题。听力学家通过培训和经验有资格协助听力损失儿童的评估和康复。 |

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| (4) Technical data. Technical data useful in selecting, fitting, and checking the performance of a hearing aid shall be provided in the User Instructional Brochure or in separate labeling that accompanies the device. The determination of technical data values for the hearing aid labeling shall be conducted in accordance with the test procedures of the American National Standard “Specification of Hearing Aid Characteristics,” ANSI S3.22-2003 (Revision of ANSI S3.22-1996) (Includes April 2007 Erratum). The Director of the Office of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the Standards Secretariat of the Acoustical Society of America, 120 Wall St., New York, NY 10005-3993, or are available for inspection at the Regulations Staff, CDRH (HFZ-215), FDA, 1350 Piccard Dr., rm. 150, Rockville, MD 20850, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html. As a minimum, the User Instructional Brochure or such other labeling shall include the appropriate values or information for the following technical data elements as these elements are defined or used in such standard: | (4)技术数据。 有助于选择、安装和检查助听器性能的技术数据应在用户指导手册或设备随附的单独标签中提供。助听 器标签技术数据值的确定，应按照美国国家标准《助听器特性规范》ANSI S3.22-2003（ANSI S3.22-1996修订版） 的测试程序进行（包括 2007 年 4 月的勘误表）。联邦公报办公室主任根据 5 USC 552(a) 和 1 CFR 第 51 部分 通过引用批准此合并。副本可从纽约华尔街 120 号美国声学学会标准秘书处获得, NY 10005-3993, 或可向 FDA 的 法规人员、CDRH (HFZ-215)、1350 皮卡德博士，rm。150, Rockville, MD 20850，或在国家档案和记录管理局 (NARA)。有关在 NARA 获取此材料的信息，请致电 202-741-6030，或访问：http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html。 作为最低限度，用户说明手册或此类其他标签应包括以下技术数据元素的适当值或信息，因为这些元素在此类标准中定义 或使用： |
| (i) Saturation output curve (SSPL 90 curve). | (i) 饱和输出曲线（SSPL 90 曲线）。 |
| (ii) Frequency response curve. | (ii) 频率响应曲线。 |
| (iii) Average saturation output (HF-Average SSPL 90). | (iii) 平均饱和输出（HF-Average SSPL 90）。 |
| (iv) Average full-on gain (HF-Average full-on gain). | (iv) 平均全开增益（HF-Average full-on gain）。 |
| (v) Reference test gain. | (v) 参考测试增益。 |
| (vi) Frequency range. | (vi) 频率范围。 |
| (vii) Total harmonic distortion. | (vii) 总谐波失真。 |
| (viii) Equivalent input noise. | (viii) 等效输入噪声。 |
| (ix) Battery current drain. | (ix) 电池电流消耗。 |
| (x) Induction coil sensitivity (telephone coil aids only). | (x) 感应线圈灵敏度（仅限电话线圈辅助设备）。 |
| (xi) Input-output curve (ACG aids only). | (xi) 输入-输出曲线（仅限 ACG 辅助工具）。 |
| (xii) Attack and release times (ACG aids only). | (xii) 攻击和释放时间（仅限 ACG 辅助）。 |
| (5) Statement if hearing aid is used or rebuilt. If a hearing aid has been used or rebuilt, this fact shall be declared on the container in which the hearing aid is packaged and on a tag that is physically attached to such hearing aid. Such fact may also be stated in the User Instructional Brochure. | (5)是否使用或重建助听器的声明。 如果助听器已被使用或重建，则应在包装助听器的容器上和附在助听器上的标签上 声明这一事实。此类事实也可能在用户指导手册中说明。 |

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| (6) Statements in User Instructional Brochure other than those required. A User Instructional Brochure may contain statements or illustrations in addition to those required by paragraph (c) of this section if the additional statements: | (6)用户指导手册中除要求外的陈述。 如果附加声明： |
| (i) Are not false or misleading in any particular, e.g., diminishing the impact of the required statements; and | (i) 在任何特定方面不存在虚假或误导性，例如，减少所需陈述的影响；和 |
| (ii) Are not prohibited by this chapter or by regulations of the Federal Trade Commission. | (ii) 不受本章或联邦贸易委员会法规的禁止。 |
| **§ 801.421 Hearing aid devices; conditions for sale.** | **801.421 助听器；出售条件。** |
| (a) Medical evaluation requirements -(1) General. Except as provided in paragraph (a)(2) of this section, a hearing aid dispenser shall not sell a hearing aid unless the prospective user has presented to the hearing aid dispenser a written statement signed by a licensed physician that states that the patient's hearing loss has been medically evaluated and the patient may be considered a candidate for a hearing aid. The medical evaluation must have taken place within the preceding 6 months. | (a)医学评估要求 - (1)一般。 除本节 (a)(2) 段规定外，助听器配售者不得出售助听器，除非准用户已向助听器配 售者出示由执业医师签署的书面声明，说明患者的听力损失已经过医学评估，患者可能被认为是助听器的候选人。医学评估必须在前 6 个月内进行。 |
| (2) Waiver to the medical evaluation requirements. If the prospective hearing aid user is 18 years of age or older, the hearing aid dispenser may afford the prospective user an opportunity to waive the medical evaluation requirement of paragraph (a)(1) of this section provided that the hearing aid dispenser: | (2)免除医学评估要求。 如果准助听器用户年满 18 岁，助听器配药师可以让准用户有机会放弃本节 (a)(1) 段的医 学评估要求，前提是助听器配药师： |
| (i) Informs the prospective user that the exercise of the waiver is not in the user's best health interest; | (i) 通知潜在用户行使弃权不符合用户的最佳健康利益； |
| (ii) Does not in any way actively encourage the prospective user to waive such a medical evaluation; and | (ii) 不以任何方式积极鼓励潜在用户放弃此类医学评估；和 |
| (iii) Affords the prospective user the opportunity to sign the following statement:<br>I have been advised by ____ ____ (Hearing aid dispenser's name) that the Food and Drug Administration has determined that my best health interest would be served if I had a medical evaluation by a licensed physician (preferably a physician who specializes in diseases of the ear) before purchasing a hearing aid. I do not wish a medical evaluation before purchasing a hearing aid. | (iii) 为潜在用户提供签署以下声明的机会：<br>____ ____（助听器配药师的名字）告诉我，食品和药物管理局已确定，如果我得到有执照的医生（最好是专攻耳部疾 病的医生）的医学评估，我的健康利益将得到最大保障) 在购买助听器之前。我不希望在购买助听器之前进行医学评 估。 |
| (b) Opportunity to review User Instructional Brochure. Before signing any statement under paragraph (a)(2)(iii) of this section and before the sale of a hearing aid to a prospective user, the hearing aid dispenser shall: | (b)审查用户指导手册的机会。 在根据本节 (a)(2)(iii) 段签署任何声明之前以及在将助听器出售给潜在用户之前， 助听器分配器应： |
| (1) Provide the prospective user a copy of the User Instructional Brochure for a hearing aid that has been, or may be selected for the prospective user; | (1) 向潜在用户提供已为或可能为潜在用户选择的助听器的用户指导手册的副本； |
| (2) Review the content of the User Instructional Brochure with the prospective user orally, or in the predominate method of | (2) 与潜在用户口头或以销售期间使用的主要沟 |

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| communication used during the sale; | 通方式审查用户使用说明书的内容； |
| (3) Afford the prospective user an opportunity to read the User Instructional Brochure. | (3) 为潜在用户提供阅读用户说明手册的机会。 |
| (c) Availability of User Instructional Brochure. | (c)用户指导手册的可用性。 |
| (1) Upon request by an individual who is considering purchase of a hearing aid, a dispenser shall, with respect to any hearing aid that he dispenses, provide a copy of the User Instructional Brochure for the hearing aid or the name and address of the manufacturer or distributor from whom a User Instructional Brochure for the hearing aid may be obtained. | (1) 应考虑购买助听器的个人的要求，配售者应就其配售的任何助听器提供该助听器的用 户使用说明书的副本，或者提供该助听器的名称和地址。助听器用户指导手册的制造商或分销商。 |
| (2) In addition to assuring that a User Instructional Brochure accompanies each hearing aid, a manufacturer or distributor shall with respect to any hearing aid that he manufactures or distributes: | (2) 除了保证每台助听器都附有用户指导手册外，制造商或分销商应就其制造或分销的任何助听器： |
| (i) Provide sufficient copies of the User Instructional Brochure to sellers for distribution to users and prospective users; | (i) 向卖家提供足够的用户说明手册副本，以便分发给用户和潜在用户； |
| (ii) Provide a copy of the User Instructional Brochure to any hearing aid professional, user, or prospective user who requests a copy in writing. | (ii) 向任何以书面形式索取副本的助听器专业人员、用户或潜在用户提供用户指导手册的副本。 |
| (d) Recordkeeping. The dispenser shall retain for 3 years after the dispensing of a hearing aid a copy of any written statement from a physician required under paragraph (a)(1) of this section or any written statement waiving medical evaluation required under paragraph (a)(2)(iii) of this section. | (d) 记录保存。 配药员应在配发助听器后保留本节 (a)(1) 段要求的医生的任何书面声明的副本或 (a)(2) 段要求的 放弃医学评估的任何书面声明的副本)(iii) 本条。 |
| (e) Exemption for group auditory trainers. Group auditory trainers, defined as a group amplification system purchased by a qualified school or institution for the purpose of communicating with and educating individuals with hearing impairments, are exempt from the requirements of this section. | (e) 团体听觉训练师的豁免。 团体听觉训练器，定义为由合格的学校或机构购买的用于与听力障碍人士交流和教育的团 体放大系统，不受本节要求的约束。 |
| **§ 801.430 User labeling for menstrual tampons.** | **801.430 月经卫生棉条的用户标签。** |
| (a) This section applies to scented or scented deodorized menstrual tampons as identified in § 884.5460 and unscented menstrual tampons as identified in § 884.5470 of this chapter. | (a) 本节适用于第 884.5460 条中确定的有香味或有香味的除臭月经卫生棉条，以及本章第 884.5470 条中确定的无 香味月经卫生棉条。 |
| (b) Data show that toxic shock syndrome (TSS), a rare but serious and sometimes fatal disease, is associated with the use of menstrual tampons. To protect the public and to minimize the serious adverse effects of TSS, menstrual tampons shall be labeled as set forth in paragraphs (c), (d), and (e) of this section and tested for absorbency as set forth in paragraph (f) of this section. | (b) 数据显示，中毒性休克综合征 (TSS) 是一种罕见但严重且有时是致命的疾病，与使用月经卫生棉条有关。为了保 护公众和尽量减少 TSS 的严重不良影响，月经棉条应按照本节 (c)、(d) 和 (e) 段的规定贴上标签，并按照 (f) 段的规定进行吸收性测试) 本节。 |
| (c) If the information specified in paragraph (d) of this section is to be included as a package insert, the following alert statement shall appear prominently and legibly on the package label:<br>ATTENTION: Tampons are associated with Toxic Shock Syndrome (TSS). TSS is a rare but serious disease that may | (c) 如果本节 (d) 段中规定的信息作为包装插页包含，则以下警示声明应在包装标签上醒目和清晰地出现： 注意：卫生棉条与中毒性休克综合征 (TSS) 有关。TSS 是一种罕见但可能导致 |

<table>
<tr><td>cause death. Read and save the enclosed information.</td><td>死亡的严重疾病。阅读并保存随附的信 息。</td></tr>
<tr><td>(d) The labeling of menstrual tampons shall contain the following consumer information prominently and legibly, in such terms as to render the information likely to be read and understood by the ordinary individual under customary conditions of purchase and use:</td><td>(d) 月经棉条的标签应以醒目、清晰的方式包含以下消费者信息，以使普通个人在购买和使用的习惯条件下易于阅读和 理解：</td></tr>
<tr><td>(1) (i) Warning signs of TSS, e.g., sudden fever (usually 102° or more) and vomiting, diarrhea, fainting or near fainting when standing up, dizziness, or a rash that looks like a sunburn;</td><td>(1)(i) TSS 的警告信号，例如突然发烧（通常为 102 度或更高）和呕吐、腹泻、站立时昏厥或几乎昏厥、头晕或看 起来像晒伤的皮疹；</td></tr>
<tr><td>(ii) What to do if these or other signs of TSS appear, including the need to remove the tampon at once and seek medical attention immediately;</td><td>(ii) 如果出现这些或其他 TSS 迹象该怎么办，包括需要立即取出卫生棉条并立即就医；</td></tr>
<tr><td>(2) The risk of TSS to all women using tampons during their menstrual period, especially the reported higher risks to women under 30 years of age and teenage girls, the estimated incidence of TSS of 1 to 17 per 100,000 menstruating women and girls per year, and the risk of death from contracting TSS;</td><td>(2) 所有在月经期间使用卫生棉条的女性发生 TSS 的风险，特别是据报道对 30 岁以下女性和少女的风险更高，估计 每年每 100,000 名经期妇女和女孩中有 1 至 17 人发生 TSS ，以及感染 TSS 的死亡风险；</td></tr>
<tr><td>(3) The advisability of using tampons with the minimum absorbency needed to control menstrual flow in order to reduce the risk of contracting TSS;</td><td>(3) 建议使用具有控制月经流量所需的最低吸水性的卫生棉条，以降低患 TSS 的风险；</td></tr>
<tr><td>(4) Avoiding the risk of getting tampon-associated TSS by not using tampons, and reducing the risk of getting TSS by alternating tampon use with sanitary napkin use during menstrual periods; and</td><td>(4) 通过不使用卫生棉条来避免与卫生棉条相关的 TSS 的风险，并通过在月经期间交替使用卫生棉条和使用卫生巾来 降低 TSS 的风险；和</td></tr>
<tr><td>(5) The need to seek medical attention before again using tampons if TSS warning signs have occurred in the past, or if women have any questions about TSS or tampon use.</td><td>(5) 如果过去曾出现过 TSS 警告信号，或者女性对 TSS 或卫生棉条的使用有任何疑问，在再次使用卫生棉条前需要 就医。</td></tr>
<tr><td>(e) The statements required by paragraph (e) of this section shall be prominently and legibly placed on the package label of menstrual tampons in conformance with section 502(c) of the Federal Food, Drug, and Cosmetic Act (the act) (unless the menstrual tampons are exempt under paragraph (g) of this section).</td><td>(e) 本节 (e) 段要求的声明应根据《联邦食品、药品和化妆品法》（该法案）第 502(c) 节的规定，醒目且清晰地放 置在月经棉条的包装标签上（除非月经棉条根据本节 (g) 段获得豁免）。</td></tr>
<tr><td>(1)Menstrual tampon package labels shall bear one of the following absorbency terms representing the absorbency of the production run, lot, or batch as measured by the test described in paragraph (f)(2) of this section;
<table>
<tr><td>Ranges of absorbency in grams1</td><td>Corresponding term of absorbency</td></tr>
<tr><td>6 and under</td><td>Light absorbency</td></tr>
<tr><td>6 to 9</td><td>Regular absorbency</td></tr>
<tr><td>9 to 12</td><td>Super absorbency</td></tr>
<tr><td>12 to 15</td><td>Super plus absorbency</td></tr>
<tr><td>15 to 18</td><td>Ultra absorbency</td></tr>
</table></td><td>(1)月经棉条的包装标签应带有以下吸收度术语之一，表示通过本节 (f)(2) 段所述测试测量的生产运行、批次或批 次的吸收度；
<table>
<tr><td>以克为单位的吸收范围</td><td>吸水率对应项</td></tr>
<tr><td>6岁及以下</td><td>吸光度</td></tr>
<tr><td>6到9</td><td>常规吸水性</td></tr>
<tr><td>9到12</td><td>超强吸水性</td></tr>
<tr><td>12 至 15</td><td>超强吸水性</td></tr>
<tr><td>15 至 18</td><td>超吸水性</td></tr>
</table></td></tr>
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| Above 18 | No term |
| 1These ranges are defined, respectively, as follows: Less than or equal to 6 grams (g); greater than 6 g up to and including 9 g; greater than 9 g up to and including 12 g; greater than 12 g up to and including 15 g; greater than 15 g up to and including 18 g; and greater than 18 g. | |

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| 18岁以上 | 没有期限 |
| 1 这些范围分别定义如下： 小于或等于 6 克 (g)；大于 6 克至 9 克；大于 9 克至 12 克；大于 12 克，不超过 15 克；大于 15 克，不超过 18 克；并且大于 18 克。 | |

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| (2) The package label shall include an explanation of the ranges of absorbency and a description of how consumers can use a range of absorbency, and its corresponding absorbency term, to make comparisons of absorbency of tampons to allow selection of the tampons with the minimum absorbency needed to control menstrual flow in order to reduce the risk of contracting TSS. | (2) 包装标签应包括对吸收范围的说明，以及消费者如何使用吸收范围及其相应的吸收术语的说明，以比较卫生棉条的 吸收能力，以便选择最低限度的卫生棉条。控制月经流量以降低患 TSS 的风险所需的吸收能力。 |
| (f) A manufacturer shall measure the absorbency of individual tampons using the test method specified in paragraph (f)(2) of this section and calculate the mean absorbency of a production run, lot, or batch by rounding to the nearest 0.1 gram. | (f) 制造商应使用本节 (f)(2) 段中规定的测试方法测量单个卫生棉条的吸水性，并通过四舍五入到最接近的 0.1 克 计算生产运行、批次或批次的平均吸水性。 |
| (1) A manufacturer shall design and implement a sampling plan that includes collection of probability samples of adequate size to yield consistent tolerance intervals such that the probability is 90 percent that at least 90 percent of the absorbencies of individual tampons within a brand and type are within the range of absorbency stated on the package label. | (1) 制造商应设计和实施抽样计划，其中包括收集足够大小的概率样本，以产生一致的公差区间，从而使品牌和类型内 的单个卫生棉条的至少 90% 的吸收率达到 90% 的概率为 90%。在包装标签上标明的吸光度范围内。 |
| (2) In the absorbency test, an unlubricated condom, with tensile strength between 17 Mega Pascals (MPa) and 30 MPa, as measured according to the procedure in the American Society for Testing and Materials (ASTM) D 3492-97, “Standard Specification for Rubber Contraceptives (Male Condoms)”[1] for determining tensile strength, which is incorporated by reference in accordance with 5 U.S.C. 552(a), is attached to the large end of a glass chamber (or a chamber made from hard transparent plastic) with a rubber band (see figure 1) and pushed through the small end of the chamber using a smooth, finished rod. The condom is pulled through until all slack is removed. The tip of the condom is cut off and the remaining end of the condom is stretched over the end of the tube and secured with a rubber band. A preweighed (to the nearest 0.01 gram) tampon is placed within the condom membrane so that the center of gravity of the tampon is at the center of the chamber. An infusion needle (14 gauge) is inserted through the septum created by the condom tip until it contacts the end of the tampon. The outer chamber is filled with water pumped from a temperature-controlled waterbath to maintain the average temperature at 27±1 °C. The water returns to the waterbath as shown in figure 2. Syngyna fluid (10 grams sodium chloride, 0.5 gram Certified Reagent Acid Fushsin, 1,000 milliliters distilled water) is then pumped through the infusion needle at a rate of 50 milliliters per hour. The test shall be terminated when the tampon is saturated and the first drop of fluid exits the apparatus. (The test result shall be discarded if fluid is detected in the folds of the condom before the tampon is saturated). The water is then drained and the tampon is removed and immediately weighed to the nearest | (2) 在吸收性测试中，根据美国材料与试验协会 (ASTM) D 3492-97，“标准橡胶避孕药（男用避孕套）规范” 1 用 于确定抗拉强度，根据 5 USC 552(a) 通过引用并入，用橡皮筋附在玻璃室（或由硬透明塑料制成的室）的大端（见 图 1）和使用光滑的成品杆将其推过腔室的小端。避孕套被拉过，直到所有松弛都被消除。将避孕套的尖端剪掉，将避 孕套的另一端套在管子的末端，并用橡皮筋固定。将预先称重（精确到 0.01 克）的卫生棉条放置在避孕套膜内，使卫 生棉条的重心位于腔室的中心。一根输液针（14 号）穿过避孕套尖端形成的隔膜，直到它接触到卫生棉条的末端。外室 充满了从温控水浴中抽出的水，以将平均温度保持在 27+/-1 摄氏度。水如图 2 所示返回水浴。然后以 50 毫升 /小 时的速度将 Syngyna 液体（10 克氯化钠、0.5 克认证试剂酸 Fushsin、1,000 毫升蒸馏水）泵入输液针头。当卫 生棉条饱和并且第一滴液体流出设备时，测试应终止。（如果在卫生棉条饱和之前在避孕套的褶皱中检测到液体，则测 试结果将被丢弃）。然后将水排干，取出棉塞并立即称重至最接近的 0.01 克。通过从该值中减去其干重来确定卫生棉 条的吸水性。 |

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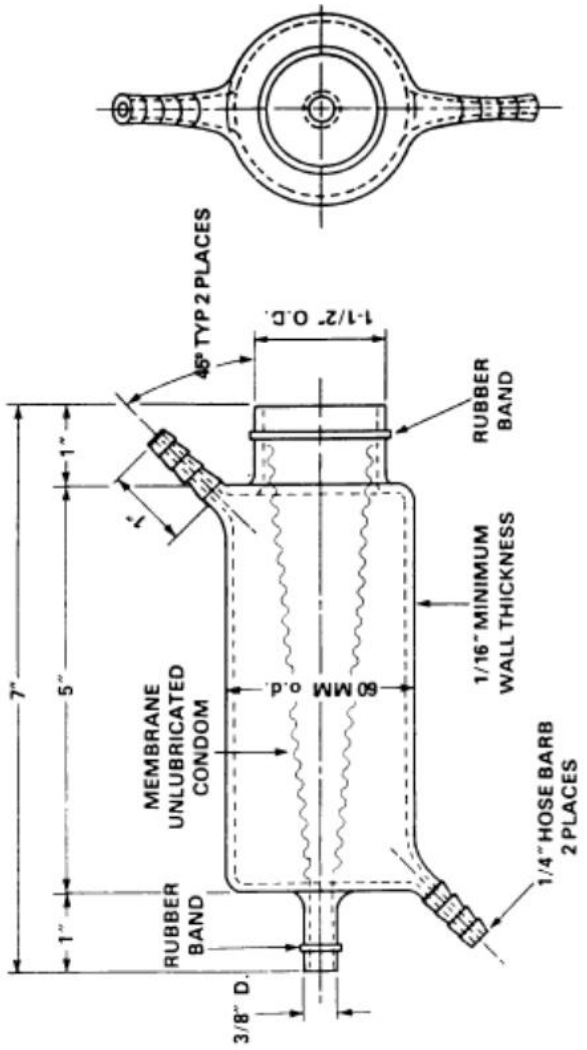
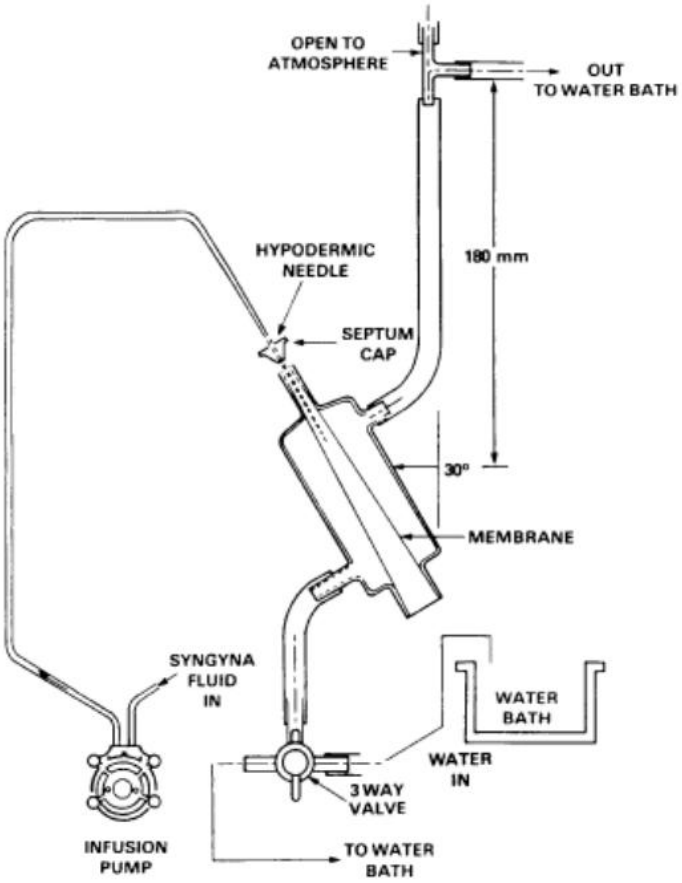
| 0.01 gram. The absorbency of the tampon is determined by subtracting its dry weight from this value. The condom shall be replaced after 10 tests or at the end of the day during which the condom is used in testing, whichever occurs first. | |
|  <br>FIGURE 1 – SYNGYNA TEST CHAMBER<br>  <br>FIGURE 2—SYNGYNA TEST SET-UP | |
| [1]The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain a copy from the American Society for Testing and Materials International, 100 Barr Harbor Dr., P.O. Box C700, West Conshohocken, PA 19428-2959, 610-832-9578, www.astm.org. You may inspect a copy at the FDA Main Library, 10903 New Hampshire Ave., Bldg. 2, 3d floor, Silver Spring, MD 20993-0002, 301-796-2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-2139, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html. | 1 联邦公报主任根据 5 USC 552(a) 和 1 CFR 第 51 部分通过引用批准此合并。您可以从美国国际测试与材料协会 获得一份副本，地址为 100 Barr Harbour Dr., PO Box C700, West Conshohocken, PA 19428-2959, 610- 832-9578, www.astm.org。 您可以在 FDA Main Library, 10903 New Hampshire Ave., Bldg 查看一份副 本。2, 3d floor, Silver Spring, MD 20993-0002, 301-796-2039，或在国家档案和记录管理局 (NARA)。有 关在 NARA 获得此材料的信息，请致电 202-741-2139，或访问：http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html。 |
| (3) The Food and Drug Administration may permit the use of an absorbency test method different from the test method specified | (3) 满足下列条件的，食品药品监督管理局可以允许使用不同于本条规定的测试方法的吸光度 |

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| in this section if each of the following conditions is met: | 测试方法： |
| (i) The manufacturer presents evidence, in the form of a citizen petition submitted in accordance with the requirements of § 10.30 of this chapter, demonstrating that the alternative test method will yield results that are equivalent to the results yielded by the test method specified in this section; and | (i) 制造商提供证据，以根据本章 § 10.30 的要求提交的公民请愿书的形式，证明替代测试方法将产生与第本节; 和 |
| (ii) FDA approves the method and has published notice of its approval of the alternative test method in the FEDERAL REGISTER. | (ii) FDA 批准该方法，并在联邦公报上发布了批准替代测试方法的通知。 |
| (g) Any menstrual tampon intended to be dispensed by a vending machine is exempt from the requirements of this section. | (g) 任何打算由自动售货机分发的月经卫生棉条均不受本节要求的约束。 |
| (h) Any menstrual tampon that is not labeled as required by paragraphs (c), (d), and (e) of this section and that is initially introduced or initially delivered for introduction into commerce after March 1, 1990, is misbranded under sections 201(n), 502 (a) and (f) of the act. | (h) 任何未按本节 (c)、(d) 和 (e) 段要求贴上标签的月经卫生棉条，并且在 1990 年 3 月 1 日之后首次引入或 最初交付用于商业化的，都被贴错标签该法第 201(n)、502 (a) 和 (f) 条。 |
| (Information collection requirements contained in paragraphs (e) and (f) were approved by the Office of Management and Budget under control number 0910-0257) | （（e）和（f）段所载信息收集要求已由管理和预算厅核准，管制号为 0910-0257） |
| **§ 801.433 Warning statements for prescription and restricted device products containing or manufactured with chlorofluorocarbons or other ozone-depleting substances.** | **801.433 含有或使用氯氟烃或其他消耗臭氧层物质制造的处方和受限器械产品的警告声明。** |
| (a)(1) All prescription and restricted device products containing or manufactured with chlorofluorocarbons, halons, carbon tetrachloride, methyl chloride, or any other class I substance designated by the Environmental Protection Agency (EPA) shall, except as provided in paragraph (b) of this section, bear the following warning statement:<br><br>WARNING: Contains [or Manufactured with, if applicable] [insert name of substance], a substance which harms public health and environment by destroying ozone in the upper atmosphere. | (a)(1) 所有含有或使用氯氟烃、哈龙、四氯化碳、氯甲烷或环境保护署 (EPA) 指定的任何其他 I 类物质制造的处方 药和受限器械产品，除 (b) 段规定外，均应) 的本节，带有以下警告声明：<br><br>警告：包含 [或制造，如果适用] [插入物质名称]，一种通过破坏高层大气中的臭氧来危害公众健康和环境的物质。 |
| (2) The warning statement shall be clearly legible and conspicuous on the product, its immediate container, its outer packaging, or other labeling in accordance with the requirements of 40 CFR part 82 and appear with such prominence and conspicuousness as to render it likely to be read and understood by consumers under normal conditions of purchase. | (2) 根据 40 CFR 第 82 部分的要求，警告声明应在产品、其直接容器、其外包装或其他标签上清晰易读且醒目，并 以使其可能消费者在正常购买条件下阅读和理解。 |
| (b) (1) For prescription and restricted device products, the following alternative warning statement may be used: | (b)(1) 对于处方药和受限器械产品，可以使用以下替代警告声明： |
| The indented statement below is required by the Federal government's Clean Air Act for all products containing or manufactured with chlorofluorocarbons (CFC's) [or name of other class I substance, if applicable]: | 联邦政府的《清洁空气法》要求所有含有或使用氯氟烃 (CFC) [或其他 I 类物质的名称，如果适用] 的产品制造以下 缩进声明： |
| This product contains [or is manufactured with, if applicable] [insert name of substance], a substance which harms the | 本产品包含 [或在制造时使用，如果适用的话] [插入物质名称]，一种通过破坏高层大气中的臭 |

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| environment by destroying ozone in the upper atmosphere. | 氧来危害环境的物质。 |
| Your physician has determined that this product is likely to help your personal health. USE THIS PRODUCT AS DIRECTED, UNLESS INSTRUCTED TO DO OTHERWISE BY YOUR PHYSICIAN. If you have any questions about alternatives, consult with your physician. | 您的医生已确定该产品可能有助于您的个人健康。请按照指示使用本产品，除非您的医生另有指示。如果您对替代品有 任何疑问，请咨询您的医生。 |
| (2) The warning statement shall be clearly legible and conspicuous on the product, its immediate container, its outer packaging, or other labeling in accordance with the requirements of 40 CFR part 82 and appear with such prominence and conspicuousness as to render it likely to be read and understood by consumers under normal conditions of purchase. | (2) 根据 40 CFR 第 82 部分的要求，警告声明应在产品、其直接容器、其外包装或其他标签上清晰易读且醒目，并 以使其可能消费者在正常购买条件下阅读和理解。 |
| (3) If the warning statement in paragraph (b)(1) of this section is used, the following warning statement must be placed on the package labeling intended to be read by the physician (physician package insert) after the “How supplied” section, which describes special handling and storage conditions on the physician labeling: | (3) 如果使用本节 (b)(1) 段中的警告声明，则必须在“如何提供”之后将以下警告声明放置在打算由医生阅读的包装 标签上（医生包装插页）部分，描述了医师标签上的特殊处理和储存条件： |
| Note: The indented statement below is required by the Federal government's Clean Air Act for all products containing or manufactured with chlorofluorocarbons (CFC's) [or name of other class I substance, if applicable]: | 笔记：联邦政府的《清洁空气法》要求所有含有或使用氯氟烃 (CFC) [或其他 I 类物质的名称，如果适用] 的产品制造以下 缩进声明： |
| WARNING: Contains [or Manufactured with, if applicable] [insert name of substance], a substance which harms public health and environment by destroying ozone in the upper atmosphere. | 警告：包含 [或制造，如果适用] [插入物质名称]，一种通过破坏高层大气中的臭氧来危害公众健康和环境的物质。 |
| A notice similar to the above WARNING has been placed in the information for the patient [or patient information leaflet, if applicable] of this product under Environmental Protection Agency (EPA) regulations. The patient's warning states that the patient should consult his or her physician if there are questions about alternatives | 根据环境保护署 (EPA) 的规定，已在本产品的患者信息 [或患者信息手册，如果适用] 中放置了与上述警告类似的通 知。患者的警告指出，如果对替代方案有疑问，患者应咨询他或她的医生。 |
| (c) This section does not replace or relieve a person from any requirements imposed under 40 CFR part 82. | (c) 本节不取代或免除某人根据 40 CFR 第 82 部分施加的任何要求。 |
| **§ 801.435 User labeling for latex condoms** | **801.435 乳胶避孕套的用户标签。** |
| (a) This section applies to the subset of condoms as identified in § 884.5300 of this chapter, and condoms with spermicidal lubricant as identified in § 884.5310 of this chapter, which products are formed from latex films. | (a) 本节适用于本章第 884.5300 节中确定的避孕套子集，以及本章第 884.5310 节中确定的带有杀精润滑剂的避孕 套，这些产品由乳胶薄膜制成。 |
| (b) Data show that the material integrity of latex condoms degrade over time. To protect the public health and minimize the risk of device failure, latex condoms must bear an expiration date which is supported by testing as described in paragraphs (d) and (h) of this section. | (b) 数据显示，乳胶避孕套的材料完整性会随着时间的推移而退化。为保护公众健康并将设备故障的风险降至最低，乳 胶避孕套必须有一个有效期，该有效期由本节 (d) 和 (h) 段所述的测试支持。 |
| (c) The expiration date, as demonstrated by testing procedures required by paragraphs (d) and (h) of this section, must be | (c) 如本节 (d) 和 (h) 段要求的测试程序所证明 |

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| displayed prominently and legibly on the primary packaging (i.e., individual package), and higher levels of packaging (e.g., boxes of condoms), in order to ensure visibility of the expiration date by consumers. | 的，有效期必须在初级包装（即单个包装）和更高级别的包装（例 如，避孕套盒），以确保消费者对有效期的可见性。 |
| (d) Except as provided under paragraph (f) of this section, the expiration date must be supported by data demonstrating physical and mechanical integrity of the product after three discrete and representative lots of the product have been subjected to each of the following conditions: | (d) 除本节 (f) 段规定的情况外，有效期必须有数据证明产品的三个离散且有代表性的批次经受以下每个条件后产品 的物理和机械完整性： |
| (1) Storage of unpackaged bulk product for the maximum amount of time the manufacturer allows the product to remain unpackaged, followed by storage of the packaged product at 70 °C (plus or minus 2 °C) for 7 days; | (1) 未包装散装产品在制造商允许产品保持未包装状态的最长时间内储存，然后将包装产品在 70 摄氏度（正负 2 摄 氏度）下储存 7 天； |
| (2) Storage of unpackaged bulk product for the maximum amount of time the manufacturer allows the product to remain unpackaged, followed by storage of the packaged product at a selected temperature between 40 and 50 °C (plus or minus 2 °C) for 90 days; and | (2) 未包装散装产品在制造商允许产品保持未包装状态的最长时间内储存，然后将包装产品储存在 40 至 50 摄氏度 （正负 2 摄氏度）之间的选定温度下90天；和 |
| (3) Storage of unpackaged bulk product for the maximum amount of time the manufacturer allows the product to remain unpackaged, followed by storage of the packaged product at a monitored or controlled temperature between 15 and 30 °C for the lifetime of the product (real time storage). | (3) 未包装的散装产品在制造商允许产品保持未包装的最长时间内储存，然后在产品的整个生命周期内将包装的产品储 存在 15 至 30 摄氏度之间的监控或控制温度下（实时存储）。 |
| (e) If a product fails the physical and mechanical integrity tests commonly used by industry after the completion of the accelerated storage tests described in paragraphs (d)(1) and (d)(2) of this section, the product expiration date must be demonstrated by real time storage conditions described in paragraph (d)(3) of this section. If all of the products tested after storage at temperatures as described in paragraphs (d)(1) and (d)(2) of this section pass the manufacturer's physical and mechanical integrity tests, the manufacturer may label the product with an expiration date of up to 5 years from the date of product packaging. If the extrapolated expiration date under paragraphs (d)(1) and (d)(2) of this section is used, the labeled expiration date must be confirmed by physical and mechanical integrity tests performed at the end of the stated expiration period as described in paragraph (d)(3) of this section. If the data from tests following real time storage described in paragraph (d)(3) of this section fails to confirm the extrapolated expiration date, the manufacturer must, at that time, relabel the product to reflect the actual shelf life. | (e) 如果产品在完成本节 (d)(1) 和 (d)(2) 中所述的加速储存测试后未能通过工业常用的物理和机械完整性测试， 则产品有效期必须通过本节 (d)(3) 段中描述的实时存储条件来证明。如果在本节 (d)(1) 和 (d)(2) 所述的温度下 储存后测试的所有产品都通过了制造商的物理和机械完整性测试，则制造商可以在产品标签上标明有效期为自产品包装 之日起最长 5 年。如果使用根据本节 (d)(1) 和 (d)(2) 段推断的到期日期，标示的有效期必须通过在本节 (d) (3) 段所述的规定有效期结束时进行的物理和机械完整性测试来确认。如果本节 (d)(3) 中描述的实时存储后的测试 数据无法确认推断的有效期，则制造商必须在那时重新标记产品以反映实际的保质期。 |
| (f) Products that already have established shelf life data based upon real time storage and testing and have such storage and testing data available for inspection are not required to confirm such data using accelerated and intermediate aging data described in paragraphs (d)(1) and (d)(2) of this section. If, however, such real time expiration dates were based upon testing of products that were not first left unpackaged for the maximum amount of time as described in paragraph (d)(3) of this section, the real time testing must be confirmed by testing products consistent with the requirements of paragraph (d)(3) of this section. This testing shall be initiated no later than the | (f) 已经建立基于实时存储和测试的保质期数据并且有此类存储和测试数据可供检查的产品，无需使用 (d)(1) 段中 描述的加速和中间老化数据确认此类数据和本节的 (d)(2)。但是，如果此类实时到期日期是基于对未在本节 (d)(3) 段中描述的最长时间内首次未包装的产品的测试，则必须通过测试确认实时测试符合本节 (d)(3) 段要求的产品。该测 试应不迟于本法规的生效日期开始。在根据本节 (d)(3) 段完成确认测试 |

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| effective date of this regulation. Until the confirmation testing in accordance with paragraph (d)(3) of this section is completed, the product may remain on the market labeled with the expiration date based upon previous real time testing. | 之前， |
| (g) If a manufacturer uses testing data from one product to support expiration dating on any variation of that product, the manufacturer must document and provide, upon request, an appropriate justification for the application of the testing data to the variation of the tested product. | (g) 如果制造商使用一种产品的测试数据来支持该产品的任何变体的有效期，则制造商必须记录并根据要求提供将测试 数据应用于被测产品变体的适当理由. |
| (h) If a latex condom contains a spermicide, and the expiration date based on spermicidal stability testing is different from the expiration date based upon latex integrity testing, the product shall bear only the earlier expiration date. | (h) 如果乳胶避孕套含有杀精剂，并且基于杀精稳定性测试的有效期与基于乳胶完整性测试的有效期不同，则产品应仅 显示较早的有效期。 |
| (i) The time period upon which the expiration date is based shall start with the date of packaging. | (i) 失效日期所依据的时间段应从包装日期开始。 |
| (j) As provided in part 820 of this chapter, all testing data must be retained in each company's files, and shall be made available upon request for inspection by the Food and Drug Administration. | (j) 根据本章第 820 部分的规定，所有检测数据必须保存在每个公司的档案中，并应食品药品监督管理局的要求提供 检查。 |
| (k) Any latex condom not labeled with an expiration date as required by paragraph (c) of this section, and initially delivered for introduction into interstate commerce after the effective date of this regulation is misbranded under sections 201(n) and 502(a) and (f) of Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(n) and 352(a) and (f)) | (k) 任何未按照本节 (c) 段的要求标明失效日期，并且在本法规生效日期后最初交付用于引入州际贸易的乳胶避孕套 在第 201(n) 和 502(a) 节下被贴错标签) 和 (f) 联邦食品、药品和化妆品法案 (21 USC 321(n) 和 352(a) 和 (f))。 |
| **§ 801.437 User labeling for devices that contain natural rubber.** | **801.437 含有天然橡胶的设备的用户标签。** |
| (a) Data in the Medical Device Reporting System and the scientific literature indicate that some individuals are at risk of severe anaphylactic reactions to natural latex proteins. This labeling regulation is intended to minimize the risk to individuals sensitive to natural latex proteins and protect the public health. | (a) 医疗器械报告系统和科学文献中的数据表明，有些人对天然乳胶蛋白存在严重过敏反应的风险。该标签法规旨在最 大程度地降低对天然乳胶蛋白敏感的个人的风险并保护公众健康。 |
| (b) This section applies to all devices composed of or containing, or having packaging or components that are composed of, or contain, natural rubber that contacts humans. The term “natural rubber” includes natural rubber latex, dry natural rubber, and synthetic latex or synthetic rubber that contains natural rubber in its formulation. | (b) 本节适用于所有由与人体接触的天然橡胶组成或包含或具有由天然橡胶组成或包含的包装或组件的设备。术语“天 然橡胶”包括天然橡胶胶乳、干燥天然橡胶和合成胶乳或在其配方中包含天然橡胶的合成橡胶。 |
| (1) The term “natural rubber latex” means rubber that is produced by the natural rubber latex process that involves the use of natural latex in a concentrated colloidal suspension. Products are formed from natural rubber latex by dipping, extruding, or coating. | (1) 术语“天然胶乳”是指通过天然胶乳工艺生产的橡胶，该工艺涉及在浓缩胶体悬浮液中使用天然胶乳。产品是由天然 橡胶胶乳通过浸渍、挤出或涂层形成的。 |
| (2) The term “dry natural rubber” means rubber that is produced by the dry natural rubber process that involves the use of coagulated natural latex in the form of dried or milled sheets. Products are formed from dry natural rubber by compression molding, extrusion, or by converting the sheets into a solution for | (2) 术语“干天然橡胶”是指通过干天然橡胶工艺生产的橡胶，该工艺涉及使用干燥或碾磨片材形式的凝结天然胶乳。产品由干燥的天然橡胶通过压缩成型、挤出或将片材转化为浸渍溶液 |

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| (3) The term “contacts humans” means that the natural rubber contained in a device is intended to contact or is likely to contact the user or patient. This includes contact when the device that contains natural rubber is connected to the patient by a liquid path or an enclosed gas path; or the device containing the natural rubber is fully or partially coated with a powder, and such powder may carry natural rubber proteins that may contaminate the environment of the user or patient. | (3) “接触人体”一词是指器械中所含的天然橡胶旨在接触或可能接触用户或患者。这包括当含有天然橡胶的设备通过液 体路径或封闭的气体路径与患者连接时的接触；或者含有天然橡胶的装置全部或部分涂有粉末，这种粉末可能携带可能 污染使用者或患者环境的天然橡胶蛋白 |
| (c) Devices containing natural rubber shall be labeled as set forth in paragraphs (d) through (h) of this section. Each required labeling statement shall be prominently and legibly displayed in conformance with section 502(c) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 352(c)). | (c) 含有天然橡胶的器械应按照本节 (d) 至 (h) 段的规定贴上标签。每个要求的标签声明都应按照《联邦食品、药 品和化妆品法》（该法案）（21 USC 352(c)）第 502(c) 节的规定突出且清晰地展示。 |
| (d) Devices containing natural rubber latex that contacts humans, as described in paragraph (b) of this section, shall bear the following statement in bold print on the device labeling: | (d) 如本节 (b) 段所述，含有与人体接触的天然橡胶胶乳的器械应在器械标签上以粗体标出以下声明： |
| “Caution: This Product Contains Natural Rubber Latex Which May Cause Allergic Reactions.” | “注意：本产品含有可能引起过敏反应的天然橡胶乳胶。” |
| This statement shall appear on all device labels, and other labeling, and shall appear on the principal display panel of the device packaging, the outside package, container or wrapper, and the immediate device package, container, or wrapper. | 该声明应出现在所有器械标签和其他标签上，并应出现在器械包装、外包装、容器或包装物以及直接器械包装、容器或 包装物的主要显示面板上。 |
| (e) Devices containing dry natural rubber that contacts humans, as described in paragraph (b) of this section, that are not already subject to paragraph (d) of this section, shall bear the following statement in bold print on the device labeling: | (e) 含有本节 (b) 段所述的与人体接触的干燥天然橡胶的器械，不受本节 (d) 段的约束，应在器械标签上以粗体字 标明以下声明： |
| “This Product Contains Dry Natural Rubber.” | “本产品含有干天然橡胶。” |
| This statement shall appear on all device labels, and other labeling, and shall appear on the principal display panel of the device packaging, the outside package, container or wrapper, and the immediate device package, container, or wrapper. | 该声明应出现在所有器械标签和其他标签上，并应出现在器械包装、外包装、容器或包装物以及直接器械包装、容器或 包装物的主要显示面板上。 |
| (f) Devices that have packaging containing natural rubber latex that contacts humans, as described in paragraph (b) of this section, shall bear the following statement in bold print on the device labeling: | (f) 如本节 (b) 段所述，包装中含有与人体接触的天然橡胶胶乳的器械，应在器械标签上以粗体字标明以下声明： |
| “Caution: The Packaging of This Product Contains Natural Rubber Latex Which May Cause Allergic Reactions.” | “注意：本产品的包装含有可能引起过敏反应的天然橡胶乳胶。” |
| This statement shall appear on the packaging that contains the natural rubber, and the outside package, container, or wrapper. | 该声明应出现在含有天然橡胶的包装以及外包装、容器或包装纸上。 |
| (g) Devices that have packaging containing dry natural rubber that contacts humans, as described in paragraph (b) of this section, shall bear the following statement in bold print on the | (g) 如本节 (b) 段所述，包装中含有与人体接触的干燥天然橡胶的器械，应在器械标签上以粗 |

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| device labeling: | 体字标明以下声明： |
| “The Packaging of This Product Contains Dry Natural Rubber.” | “本产品的包装中含有干燥的天然橡胶。” |
| This statement shall appear on the packaging that contains the natural rubber, and the outside package, container, or wrapper. | 该声明应出现在含有天然橡胶的包装以及外包装、容器或包装纸上。 |
| (h) Devices that contain natural rubber that contacts humans, as described in paragraph (b) of this section, shall not contain the term “hypoallergenic” on their labeling. | (h) 如本节 (b) 段所述，含有与人体接触的天然橡胶的器械不得在其标签上包含“低过敏性”一词。 |
| (i) Any affected person may request an exemption or variance from the requirements of this section by submitting a citizen petition in accordance with § 10.30 of this chapter. | (i) 任何受影响的人都可以根据本章第 10.30 条提交公民请愿书，请求豁免或变更本节的要求。 |
| (j) Any device subject to this section that is not labeled in accordance with paragraphs (d) through (h) of this section and that is initially introduced or initially delivered for introduction into interstate commerce after the effective date of this regulation is misbranded under sections 201(n) and 502(a), (c), and (f) of the act (21 U.S.C. 321(n) and 352(a), (c), and (f)). | (j) 任何受本节约束但未按照本节 (d) 至 (h) 段进行标记的设备，并且在本法规生效日期后最初引入或最初交付用 于引入州际贸易的任何设备被贴错标签该法案第 201(n) 和 502(a)、(c) 和 (f) 条（21 USC 321(n) 和 352(a)、(c) 和 (f)） |
| Note to § 801.437: Paragraphs (f) and (g) are stayed until June 27, 1999, as those regulations relate to device packaging that uses “cold seal” adhesives. | § 801.437 的注释：(f) 和 (g) 段保留至 1999 年 6 月 27 日，因为这些法规涉及使用“冷封”粘合剂的设备包装。 |