FDA cGMP
21 CFR 210、211

Authority: 21 U.S.C. 321, 351, 352, 355, 360b, 371, 374; 42 U.S.C. 216, 262, 263a, 264.
依据：《美国法典》第21卷第321、351、352、355、360b、371、374条，第42卷第216、262、263a、264条.

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来源：43卷《美国联邦公报》第45076页，除非另有说明;

目录

Part 210 - Current Good Manufacturing Practice In Manufacturing, Processing, Packing, Or Holding Of Drugs; General
药品制造、加工、包装或贮存cGMP总则

210.1 Status of current good manufacturing practice regulations
cGMP法规的地位（2009年12月10日）

(a) The regulations set forth in this Part and in Parts 211, 225, and 226 of this Chapter contain the minimum current good manufacturing practice for methods to be used in, and the facilities or controls to be used for, the manufacture, processing, packing, or holding of a drug to assure that such drug meets the requirements of the act as to safety, and has the identity and strength and meets the quality and purity characteristics that it purports or is represented to possess.

本部分和本卷第211、225和226部分所列条例载有目前用于制造、加工、包装或贮存药物的设施或控制的最低良好制造做法，以确保此类药物符合该法对安全性的要求，具有其特性和优势，符合其规定或所代表的质量和纯度特征。

(b) The failure to comply with any regulation set forth in this Part and in Parts 211, 225, and 226 of this Chapter in the manufacture, processing, packing, or holding of a drug shall render such drug to be adulterated under Section 501(a)(2)(B) of the act and such drug, as well as the person who is responsible for the failure to comply, shall be subject to regulatory action.

在药品的制造、加工、包装或贮存过程中，如果不遵守本部分和本卷第211、225和226部分中规定的任何规定，将导致该药品依据《美国法典》第501(a)(2)(B)（目前为21U.S.C.351）条被认定为掺假，该药品以及未能遵守该规定的责任人应受到监管行动的约束。

(c) Owners and operators of establishments engaged in the recovery, donor screening, testing (including donor testing), processing, storage, labeling, packaging, or distribution of human cells, tissues, and cellular and tissue-based products (HCT/Ps), as defined in § 1271.3(d) of this Chapter, that are drugs (subject to review under an application submitted under Section 505 of the act or under a biological product license application under Section 351 of the Public Health Service Act), are subject to the donor-eligibility and applicable current good tissue practice procedures set forth in Part 1271 Subparts C and D of this Chapter, in addition to the regulations in this Part and in Parts 211, 225, and 226 of this Chapter. Failure to comply with any applicable regulation set forth in this Part, in Parts 211, 225, and 226 of this Chapter, in Part 1271 Subpart C of this Chapter, or in Part 1271 Subpart D of this Chapter with respect to the manufacture, processing, packing or holding of a drug, renders an HCT/P adulterated under Section 501(a)(2)(B) of the act. Such HCT/P, as well as the person who is responsible for the failure to comply, is subject to regulatory action.

根据本卷第1271.3(D)节的定义，从事人体细胞、组织以及细胞和组织产品(HCT/Ps)的回收、捐赠者筛选、测试(包括捐赠者测试)、加工、贮存、标签、包装或分销的机构的所有者和经营者，是药物(根据该法第505条提交的申请或根据公共卫生服务法第351条提交的生物制品许可证申请)的所有者和经营者，必须遵守第122部分规定的捐赠者资格和适用的现行良好组织实践程序。除本部以及本章第211、225和226部分中的规定外。未能遵守本章第211、225和226部分、本章第1271节C子节或本章第1271节D节关于药品的制造、加工、包装或贮存的任何适用规定，将构成根据该法第501(A)(2)(B)节掺假的HCT/P。这些HCT/P以及未能遵守的责任人将受到监管行动的影响

[43 FR 45076, Sept. 29, 1978, as amended at 69 FR 29828, May 25, 2004; 74 FR 65431, Dec. 10, 2009]
修订历史:
1978年9月29日第43卷《美国联邦公报》45076页，
2004年5月25日第69卷《美国联邦公报》29828页，
2009年12月10日第74卷《美国联邦公报》65431页

210.2 Applicability of current good manufacturing practice regulations
cGMP法规适用范围（2009年12月10日）

(a) The regulations in this Part and in Parts 211, 225, and 226 of this Chapter as they may pertain to a drug; in Parts 600 through 680 of this Chapteras they may pertain to a biological product for human use; and in Part

1271 of this Chapter as they are applicable to a human cell, tissue, or cellular or tissue-based product (HCT/P) that is a drug (subject to review under an application submitted under Section 505 of the act or under a biological product license application under Section 351 of the Public Health Service Act); shall be considered to supplement, not supersede, each other, unless the regulations explicitly provide otherwise. In the event of a conflict between applicable regulations in this Part and in other Parts of this Chapter, the regulation specifically applicable to the drug product in question shall supersede the more general.

本部分以及本章的211、225和226节中的法规适用，药物生产有关；在本章的第600至680部分中使用，因为它们可能与人类使用的生物产品有关；在本章的第1271章节中适用，因为它们适用于作为药物的人体细胞，组织或基于细胞或组织的产品（HCT/ P）（根据该法案第505条提交的申请或根据 根据《公共卫生服务法》第351条获得的生物产品许可申请）； 除非法规另有明确规定，否则应视为相互补充，而不是相互取代。 如果本部分与本章其他部分中适用的法规发生冲突，则专门适用于所涉药品的法规为准。

(b) If a person engages in only some operations subject to the regulations in this Part, in Parts 211, 225, and 226 of this Chapter, in Parts 600 through 680 of this Chapter, and in Part 1271 of this Chapter, and not in others, that person need only comply with those regulations applicable to the operations in which he or she is engaged.

如果一个人只从事本部分、本章第211、225和226部分、本章第600至680章节以及本章第1271部分，而不是其他部分的某些业务，则此人只需遵守适用于其所从事业务的规定。

(c) An investigational drug for use in a phase 1 study, as described in § 312.21(a) of this Chapter, is subject to the statutory requirements set forth in 21 U.S.C. 351(a)(2)(B). The production of such drug is exempt from compliance with the regulations in Part 211 of this Chapter. However, this exemption does not apply to an investigational drug for use in a phase 1 study once the investigational drug has been made available for use by or for the sponsor in a phase 2 or phase 3 study, as described in § 312.21(b) and (c) of this Chapter, or the drug has been lawfully marketed. If the investigational drug has been made available in a phase 2 or phase 3 study or the drug has been lawfully marketed, the drug for use in the phase 1 study must comply with Part 211.

用于第1阶段临床研究的药物，如本章312.21(A)所述，受“美国法典”第21篇第351(A)(2)(B)节规定的法规约束。该药品的生产不受本章第211条规定限制。但是，如本章312.21(B)和(C)所述，一旦研究药物在第二阶段或第三阶段研究中提供给患者或普通志愿者受试者使用，或者药物已经合法上市，则这一豁免不适用于在第一阶段研究中使用的研究药物。如果研究药物已在第2阶段或第3阶段研究中获得，或该药物已合法上市，则在第1阶段研究中使用的药物必须符合第211部分的规定。

[69 FR 29828, May 25, 2004, as amended at 73 FR 40462, July 15, 2008; 74 FR 65431, Dec. 10, 2009]
修订历史：
2004年5月25日第69卷《美国联邦公报》29828页，
2008年7月15日第73卷《美国联邦公报》40462页，
2009年12月10日第74卷《美国联邦公报》65431 页

210.3 Definitions
定义（2009年12月10日）

(a) The definitions and interpretations contained in Section 201 of the act shall be applicable to such terms when used in this Part and in Parts 211, 225, and 226 of this Chapter.

该法第201条所载的定义和解释适用于本部分和本章第211、225和226部分使用的此类术语。

(b) The following definitions of terms apply to this Part and to Parts 211, 225, and 226 of this Chapter.

以下术语定义适用于本部分和本章第 211、225 和 226 部分。

(1) **Act**--means the Federal Food, Drug, and Cosmetic Act, as amended (21 U.S.C. 301 et seq.).

法--是指经修订的《联邦食品、药物和化妆品法》（美国法典第21卷第301条及其后各条）。

(2) **Batch**--means a specific quantity of a drug or other material that is intended to have uniform character and quality, within specified limits, and is produced according to a single manufacturing order during the same cycle of manufacture.

（整）批--是指在规定限度内，按照同一生产周期内单一制造顺序生产的具有统一性质和质量的药物或其他材料的特定数量。

(3) **Component**--means any ingredient intended for use in the manufacture of a drug product, including those that may not appear in such drug product.

成分--是指用于制造药物产品的任何成分，包括可能未出现在此类药物产品中的成分。

(4) **Drug product**--means a finished dosage form, for example, tablet, capsule, solution, etc., that contains

an active drug ingredient generally, but not necessarily, in association with inactive ingredients. The term also includes a finished dosage form that does not contain an active ingredient but is intended to be used as a placebo.

药品--指成品剂型，例如片剂、胶囊、溶液等，其通常（但不一定）含有与非活性成分相关的活性药物成分，该术语还包括不含活性成分但打算用作安慰剂的成品剂型。

(5) **Fiber--**means any Particulate contaminant with a length at least three times greater than its width.

纤维--是指长度至少大于其宽度的三倍的任何颗粒污染物。

(6) **Nonfiber releasing filter--**means any filter, which after appropriate pretreatment such as washing or flushing, will not release fibers into the component or drug product that is being filtered.

无纤维释析出过滤器--是指任何过滤器，在适当的预处理（如洗涤或冲洗）后，不会将纤维释放到正在过滤的组件或药物产品中。

(7) **Active ingredient--**means any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or other animals. The term includes those components that may undergo chemical change in the manufacture of the drug product and be present in the drug product in a modified form intended to furnish the specified activity or effect.

活性成分--指在疾病的诊断、治愈、缓解、治疗或预防中提供药理活性或其他直接作用，或影响人或其他动物身体结构或任何功能的任何成分。该术语包括那些在药品生产过程中可能发生化学变化的成分，这些成分以改性形式存在于药品中，以提供规定的活性或效果。

(8) **Inactive ingredient--**means any component other than an active ingredient.

非活性成分--是指活性成分以外的任何成分。

(9) **In-process material--**means any material fabricated, compounded, blended, or derived by chemical reaction that is produced for, and used in, the preparation of the drug product.

加工材料--是指为制备药品而制造、复合、混合或通过化学反应衍生的任何材料。

(10) **Lot--**means a batch, or a specific identified portion of a batch, having uniform character and quality within specified limits; or, in the case of a drug product produced by continuous process, it is a specific identified amount produced in a unit of time or quantity in a manner that assures its having uniform character and quality within specified limits.

批--是指一批或一批特定确定部分，在规定范围内具有统一的性质和质量：或者，对于连续加工生产的药品，则以时间或数量部门生产的特定标识量，以确保其在规定限度内具有统一的性质和质量。

(11) **Lot number, control number, or batch number--**means any distinctive combination of letters, numbers, or symbols, or any combination of them, from which the complete history of the manufacture, processing, packing, holding, and distribution of a batch or lot of drug product or other material can be determined.

批号、控制号或批号--是指任何字母、数字或符号的任意组合，或它们的任何组合，可以确定一批或大量药品或其他材料的制造、加工、包装、贮存和分销的完整历史。

(12) **Manufacture, processing, packing, or holding of a drug product--**includes packaging and labeling operations, testing, and quality control of drug products.

药品的制造、加工、包装、贮存--包括药品的包装、贴签操作、检测、质量控制。

(13) **The term medicated feed** means any Type B or Type C medicated feed as defined in § 558.3 of this Chapter. The feed contains one or more drugs as defined in Section 201(g) of the act. The manufacture of medicated feeds is subject to the requirements of Part 225 of this Chapter.

药用物料--指本章第558.3条所定义的任何B型或C型药用物料。药用物料包含该行为第201(g)节中定义的一种或多个药物。药用物料的制造须符合本章第225部分的要求。

(14) **The term medicated --**premix means a Type A medicated article as defined in § 558.3 of this Chapter. The article contains one or more drugs as defined in Section 201(g) of the act. The manufacture of medicated premixes is subject to the requirements of Part 226 of this Chapter.

药物预混合物--是指本章第 558.3 条中定义的 A 类药物。该条包含该行为第 201(g)节中定义的一种或多个药物。药物预混合物的制造应符合本章第226部分的要求。

(15) **Quality control unit--**means any person or organizational element designated by the firm to be responsible for the duties relating to quality control.

质量控制部门--是指公司指定负责质量控制职责的人员或者组织机构。

(16) **Strength means:**

规格：

(i) The concentration of the drug substance (for example, weight/weight, weight/volume, or unit dose/volume basis), and/or

药物物质的浓度（例如， 重量/重量、重量/体积或单位剂量/体积基础）和/或

(ii) The potency, that is, the therapeutic activity of the drug product as indicated by appropriate laboratory tests or by adequately developed and controlled clinical data (expressed, for example, in terms of units by reference to a standard).

效价：即根据适当的实验室检测或足够的临床研究可靠数据而得出的药品治疗活性(例如可表达为相对当于多少单位的标准物质)。

(17) **Theoretical yield--**means the quantity that would be produced at any appropriate phase of manufacture, processing, or packing of a Particular drug product, based upon the quantity of components to be used, in the absence of any loss or error in actual production.

理论产量--指在生产、加工或包装某种药品的任一适当阶段中，并且基于所使用的组分的数量在实际生产中无任何损失或错误的情况下，应能生产的数量。

(18) **Actual yield**--means the quantity that is actually produced at any appropriate phase of manufacture, processing, or packing of a Particular drug product.

实际产量--指某种药品在生产、加工、包装的任一适当的阶段实际生产出的数量。

(19) **Percentage of theoretical yield**--means the ratio of the actual yield (at any appropriate phase of manufacture, processing, or packing of a Particular drug product) to the theoretical yield (at the same phase), stated as a percentage.

理论收率的百分比--实际产量(生产、加工或包装某种药品的适当阶段)与理论产量(在相同阶段)的比率，以百分数表示。

(20) **Acceptance criteria--**means the product specifications and acceptance/rejection criteria, such as acceptable quality level and unacceptable quality level, with an associated sampling plan, that are necessary for making a decision to accept or reject a lot or batch (or any other convenient subgroups of manufactured units).

验收标准--是建立在相应的取样方法基础上的药品的质量检验标准和合格、不合格标准(如合格质量水平和不合格的质量水平)，是决定批准或拒收一批(或其他生产单元的小组)药品的必需因素。

(21) **Representative sample--**means a sample that consists of a number of units that are drawn based on rational criteria such as random sampling and intended to assure that the sample accurately portrays the material being sampled.

代表性样本--指一个样品按合理的标准抽取（如随**机取样**法），并包含若干单位（元），以能保证样品准确描绘被取样品的物料。

(22) **Gang-printed labeling--** means labeling derived from a sheet of material on which more than one item of labeling is printed.

联合印刷标签-是指从打印多个标签的材料表中提取的标签。指一张材料上打印了一项以上内容的标签。

[43 FR 45076, Sept. 29, 1978, as amended at 51 FR 7389, Mar. 3, 1986; 58 FR 41353, Aug. 3, 1993; 73 FR 51931, Sept. 8, 2008; 74 FR 65431, Dec. 10, 2009]

修订历史:

1978年9月29日第43卷《美国联邦公报》45076页，
1986年3月3日第51卷《美国联邦公报》 7389页，
1993年8月3日第58卷《美国联邦公报》41353页，
2008年9月8日第73卷《美国联邦公报》51931 页，
2009年12月10日第74卷《美国联邦公报》65431 页

Part 211 - Current Good Manufacturing Practice For Finished Pharmaceuticals

目前制剂药的cGMP

Subpart A-General Provisions

一般条款

211.1 Scope

范围（2015年9月17日）

(a) The regulations in this Part contain the minimum current good manufacturing practice for preparation of drug products (excluding positron emission tomography drugs) for administration to humans or animals.

本部分的条例载有目前为人类或动物提供药物产品制剂（不包括负电子发射断层扫描药物）的最低GMP。

(b) The current good manufacturing practice regulations in this Chapter as they pertain to drug products; in Parts 600 through 680 of this Chapter, as they pertain to drugs that are also biological products for human use; and in Part 1271 of this Chapter, as they are applicable to drugs that are also human cells, tissues, and cellular and tissue-based products (HCT/Ps) and that are drugs (subject to review under an application submitted under Section 505 of the act or under a biological product license application under Section 351 of the Public Health Service Act); supplement and do not supersede the regulations in this Part unless the regulations explicitly provide otherwise. In the event of a conflict between applicable regulations in this Part and in other Parts of this Chapter, or in Parts 600 through 680 of this Chapter, or in Part 1271 of this Chapter, the regulation specifically applicable to the drug product in question shall supersede the more general.

本部分中关于药品的现行良好生产规范法规，适用于第600至680部分，它们涉及人类使用的生物制品药物;使用于本章的1271部分，它们涉及人类细胞和组织的药物，以及基于细胞和组织的产品(HCT/Ps)和药物(根据《公共卫生服务法》第505节提交的申请或根据《公共卫生服务法》第351节提交的生物产品许可申请进行审查)；除非另有明确规定，本部分是其他部分的补充和不取代本的规定，。如果本章适用法规与本章其他部分、或600至680部分、或1271部分存在冲突，以具体适用于有关药品的规定为准。

(c) Pending consideration of a proposed exemption, published in the Federal Register of September 29, 1978, the requirements in this Part shall not be enforced for OTC drug products if the products and all their ingredients are ordinarily marketed and consumed as human foods, and which products may also fall within the legal definition of drugs by virtue of their intended use. Therefore, until further notice, regulations under Parts 110 and 117 of this Chapter, and where applicable, Parts 113 through 129 of this Chapter, shall be applied in determining whether these OTC drug products that are also foods are manufactured, processed, packed, or held under current good manufacturing practice.

在考虑经提议的，发表在 1978 年 9 月 29 日联邦注册表（FR）上一项免除时，若产品及其所有成份是以人用物品形式作一般销售和消费且这些产品根据其预期用途，亦可列入药品的范围内，则不应对这些非处方药（OTC）实施本部分条例，直至进一步的通知为止。本章110部分和113至119部分的条例用于鉴别这些同样属于食品的OTC药品是否按照cGMP的要求进行生产、加工、包装和贮存。

[43 FR 45077, Sept. 29, 1978, as amended at 62 FR 66522, Dec. 19, 1997; 69 FR 29828, May 25, 2004; 74 FR 65431, Dec. 10, 2009; 80 FR 56168, Sept. 17, 2015]

修订历史:

1978年9月29日第43卷《美国联邦公报》45077页，
1997年12月19日第62卷《美国联邦公报》 66522页，
2004年5月25日第69卷《美国联邦公报》29828页，
2009年12月10日第74卷《美国联邦公报》65431 页。
2015年9月17日第80卷《美国联邦公报》56168页。

211.3 Definitions
定义

(a) The definitions set forth in § 210.3 of this Chapter apply in this Part.

本章第210.3段中的定义适用于本部分。

Subpart B - Organization and Personnel
组织和人员

211.22 Responsibilities of quality control unit
质检控制部门的职责

(a) There shall be a quality control unit that shall have the responsibility and authority to approve or reject all components, drug product containers, closures, in-process materials, packaging material, labeling, and drug products, and the authority to review production records to assure that no errors have occurred or, if errors have occurred, that they have been fully investigated. The quality control unit shall be responsible for approving or rejecting drug products manufactured, processed, packed, or held under contract by another company.

应当有一个质量控制部门，该部门应有责任和权力来批准或拒收所有原辅料、药品容器、密封件、中间体、包

装材料、标签和药品，并有权审查生产记录以确保没有错误发生，或者如果发生错误，则对它们进行充分调查。质量控制部门负责批准或拒收由另一家公司生产，加工，包装或根据合同贮存的药品。

(b) Adequate laboratory facilities for the testing and approval (or rejection) of components, drug product containers, closures, packaging materials, in-process materials, and drug products shall be available to the quality control unit.

质量控制部门应有足够的实验室设施，用于测试和批准（或拒收）原辅料，药品容器，密封件，包装材料，中间他和药品。

(c) The quality control unit shall have the responsibility for approving or rejecting all procedures or specifications impacting on the identity, strength, quality, and purity of the drug product.

质量控制部门应负责批准或拒绝影响药品均一性，效价，质量和纯度的所有工艺或操作规程。

(d) The responsibilities and procedures applicable to the quality control unit shall be in writing; such written procedures shall be followed.

适用于本部门的职责与程序，应形成文字材料，并应遵循。

211.25 Personnel qualifications

人员资质

(a) Each person engaged in the manufacture, processing, packing, or holding of a drug product shall have education, training, and experience, or any combination thereof, to enable that person to perform the assigned functions. Training shall be in the Particular operations that the employee performs and in current good manufacturing practice (including the current good manufacturing practice regulations in this Chapter and written procedures required by these regulations) as they relate to the employee's functions. Training in current good manufacturing practice shall be conducted by qualified individuals on a continuing basis and with sufficient frequency to assure that employees remain familiar with cGMP requirements applicable to them.

从事药品生产，加工，包装或贮存的人员应受过相应的教育、培训、实践经验，或具备这些综合条件，方可从事分配的各项工作，培训应针对员工工作相关的操作以及cGMP（包括本章中cGMP，以及这些规章要求的书面程序）的要求进行，应由具备相应资质的人员指导进行cGMP知识的培训，并保持一定频率，保证员工熟悉cGMP的相关要求。

(b) Each person responsible for supervising the manufacture, processing, packing, or holding of a drug product shall have the education, training, and experience, or any combination thereof, to perform assigned functions in such a manner as to provide assurance that the drug product has the safety, identity, strength, quality, and purity that it purports or is represented to possess.

负责监督药品生产、加工、包装或贮存的人员应接受过相应的教育、培训或实践经验，或具备这些综合条件，以保证药品的安全性、均一性、效价或含量、质量以及忖度的保证。

(c) There shall be an adequate number of qualified personnel to perform and supervise the manufacture, processing, packing, or holding of each drug product.

应有足够数量的具有资质（或合格）的人员来执行和监督每种药品的制造、加工、包装或贮存。

211.28 Personnel responsibilities

人员职责

(a) Personnel engaged in the manufacture, processing, packing, or holding of a drug product shall wear clean clothing appropriate for the duties they perform. Protective apparel, such as head, face, hand, and arm coverings, shall be worn as necessary to protect drug products from contamination.

从事药品生产、加工、包装和贮存的人员，应穿着适合其操作要求的洁净服，穿着必要的防护服饰，诸如头脸部面罩、手套、护袖，以防止药物受到污染。

(b) Personnel shall practice good sanitation and health habits.

人员应有良好的卫生和健康习惯。

(c) Only personnel authorized by supervisory personnel shall enter those areas of the buildings and facilities designated as limited-access areas.

对于厂房与设施中限制入内的区域，未经管理人员允许不得入内。

(d) Any person shown at any time (either by medical examination or supervisory observation) to have an apparent illness or open lesions that may adversely affect the safety or quality of drug products shall be excluded from direct contact with components, drug product containers, closures, in-process materials, and drug products until the condition is corrected or determined by competent medical personnel not to jeopardize the safety or quality of drug products. All personnel shall be instructed to report to supervisory personnel any health conditions that may have an adverse effect on drug products.

任何人无论何时（体检或监督观察）发现有可能影响药品安全性和质量的明显疾病或开放性损伤，都应避免直

接接触各种原辅料、药品包装容器、密封件、中间体和药品，直至健康状况改善或由合格的医务人员确定其对药品的安全性和质量不会造成危害为止。所有人员应向监督人员报告所有可能对药品有不利影响的健康状况。

211.34 Consultants

顾问

(a) Consultants advising on the manufacture, processing, packing, or holding of drug products shall have sufficient education, training, and experience, or any combination thereof, to advise on the subject for which they are retained. Records shall be maintained stating the name, address, and qualifications of any consultants and the type of service they provide.

对药品的生产，加工，包装或贮存提供咨询的顾问应受过足够的教育、培训并有丰富的实践经验，或上述组合以胜任其被聘请的专业领域建议。记录应保存所有顾问的姓名、地址和资质及其提供的服务类别。

Subpart C - Buildings and Facilities

厂房和设施

211.42 Design and construction features

设计和建造要求（1995年1月20日）

(a) Any building or buildings used in the manufacture, processing, packing, or holding of a drug product shall be of suitable size, construction and location to facilitate cleaning, maintenance, and proper operations.

用于药品生产、加工、包装或贮存的厂房或建筑群均应大小适宜，建造和布局应易于清洁、维护和适宜操作。

(b) Any such building shall have adequate space for the orderly placement of equipment and materials to prevent mixups between different components, drug product containers, closures, labeling, in-process materials, or drug products, and to prevent contamination. The flow of components, drug product containers, closures, labeling, in-process materials, and drug products through the building or buildings shall be designed to prevent contamination.

建筑物应有足够的空间来有条理地安装设备和放置材料，避免不同类的原辅料、药品容器、密封件、标签、中间产品或药品之间产生混淆，并防止污染。厂房内原辅料、药品容器、密封件、标签、中间产品或药品的流向应做防污染设计

(c) Operations shall be performed within specifically defined areas of adequate size. There shall be separate or defined areas or such other control systems for the firm's operations as are necessary to prevent contamination or mixups during the course of the following procedures:

操作应在明确规定且大小适宜的区域内进行。在下列生产过程中应具备独立的或指定的区域，或者其他控制系统，来防止污染和混淆：

(1) Receipt, identification, storage, and withholding from use of components, drug product containers, closures, and labeling, pending the appropriate sampling, testing, or examination by the quality control unit before release for manufacturing or packaging;

在生产或包装放行前，质量管理部门在取样，检测或检验期间，对原辅料、药品容器、密封件及标签的接收、鉴别、贮存及禁用。

(2) Holding rejected components, drug product containers, closures, and labeling before disposition;

不合格原辅料、药品容器、密封件及标签在处理前的贮存；

(3) Storage of released components, drug product containers, closures, and labeling;

已放行的原辅料、药品容器、密封件及标签的贮存；

(4) Storage of in-process materials;

中间产品的贮存

(5) Manufacturing and processing operations;

生产和加工操作

(6) Packaging and labeling operations;

包装和贴标操作

(7) Quarantine storage before release of drug products;

药品放行前的待验贮存

(8) Storage of drug products after release;

药品放行后的贮存

(9) Control and laboratory operations;

控制和实验室操作

(10) Aseptic processing, which includes as appropriate:

无菌工艺，视情况包括

(i) Floors, walls, and ceilings of smooth, hard surfaces that are easily cleanable;
地板、墙壁和天花板应光滑，表面坚硬易清洁

(ii) Temperature and humidity controls;
温度和湿度控制

(iii) An air supply filtered through high-efficiency Particulate air filters under positive pressure, regardless of whether flow is laminar or nonlaminar;
不论是层流还是非层流，都在正压下通过高效过滤器过滤空气送风；

(iv) A system for monitoring environmental conditions;
环境检测系统

(v) A system for cleaning and disinfecting the room and equipment to produce aseptic conditions;
房间和设备的清洁，消毒系统，以产生无菌环境

(vi) A system for maintaining any equipment used to control the aseptic conditions.
控制无菌环境的设备维护系统。

(d) Operations relating to the manufacture, processing, and packing of penicillin shall be performed in facilities separate from those used for other drug products for human use.
青霉素生产、加工及包装设备与生产其他人用药品的设备分开

[43 FR 45077, Sept. 29, 1978, as amended at 60 FR 4091, Jan. 20, 1995]
修订历史：
1978年9月29日第43卷《美国联邦公报》45077页，
1995年1月20日第60卷《美国联邦公报》 4091页，

211.44 Lighting
照明

(a) Adequate lighting shall be provided in all areas.
所有区域都应提供充足的照明。

211.46 Ventilation, air filtration, air heating and cooling
通风、空气过滤、空气加热和冷却

(a) Adequate ventilation shall be provided.
应提供足够的通风

(b) Equipment for adequate control over air pressure, micro-organisms, dust, humidity, and temperature shall be provided when appropriate for the manufacture, processing, packing, or holding of a drug product.
在制造、加工、包装或贮存药品过程中，应酌情提供对压差、微生物、尘埃粒子、湿度和温度进行适当控制的设备，

(c) Air filtration systems, including prefilters and Particulate matter air filters, shall be used when appropriate on air supplies to production areas. If air is recirculated to production areas, measures shall be taken to control recirculation of dust from production. In areas where air contamination occurs during production, there shall be adequate exhaust systems or other systems adequate to control contaminants.
适当时，生产区域的送风应使用空气过滤系统，包括预过滤器和微粒空气过滤器。如果空气再循环进入生产区，应采取措施控制生产中产生的尘埃进入再循环。在生产中产生空气污染的区域，应采用足够的排气系统，或用其他系统对污染进行充分控制。

(d) Air-handling systems for the manufacture, processing, and packing of penicillin shall be completely separate from those for other drug products for human use.
青霉素生产、加工和包装区域的空气处理系统，应与其他人用药品使用的空气处理系统完全隔开

211.48 Plumbing
管道系统（1983年3月18日）

(a) Potable water shall be supplied under continuous positive pressure in a plumbing system free of defects that could contribute contamination to any drug product. Potable water shall meet the standards prescribed in the Environmental Protection Agency's Primary Drinking Water Regulations set forth in 40 CFR Part 141.

Water not meeting such standards shall not be permitted in the potable water system.
在持续正压下，用不会对任何药品造成污染的无缺陷管道系统供应饮用水。饮用水应符合《联邦行政法典》第40篇第141部分中《环境保护机构基本饮用水法》的标准规定。不符合该标准的水不得进入饮用水系统

(b) Drains shall be of adequate size and, where connected directly to a sewer, shall be provided with an air break or other mechanical device to prevent back-siphonage.
排水管道应有足够的大小，在直连污水管的地方应安装防止倒灌的空气隔断或其他机械装置，防止虹吸现象。

[43 FR 45077, Sept. 29, 1978, as amended at 48 FR 11426, Mar. 18, 1983]
修订历史：
1978年9月29日第43卷《美国联邦公报》45077页，
1983年3月18日第48卷《美国联邦公报》 11426页，

211.50 Sewage and refuse
污水和废弃物

(a) Sewage, trash, and other refuse in and from the building and immediate premises shall be disposed of in a safe and sanitary manner.
厂房和紧邻房屋内的污水、垃圾及其他废弃物，应以安全、卫生的方式处理。

211.52 Washing and toilet facilities
清洗和卫生间设施

(a) Adequate washing facilities shall be provided, including hot and cold water, soap or detergent, air driers or single-service towels, and clean toilet facilities easily accesible to working areas.
应提供充足的洗涤设施，包括热水和冷水、肥皂或清洁剂、空气干燥器或一次性用毛巾，以及便于进入工作区域的洁净厕所

211.56 Sanitation
卫生

(a) Any building used in the manufacture, processing, packing, or holding of a drug product shall be maintained in a clean and sanitary condition, Any such building shall be free of infestation by rodents, birds, insects, and other vermin (other than laboratory animals). Trash and organic waste matter shall be held and disposed of in a timely and sanitary manner.
所有用于药品生产、加工、包装及贮存的厂房应保持清洁、卫生的环境，且无啮齿类动物、鸟类、昆虫及其他害虫干扰（实验用动物除外）。应及时卫生地收集和处理垃圾和有机废物

(b) There shall be written procedures assigning responsibility for sanitation and describing in sufficient detail the cleaning schedules, methods, equipment, and materials to be used in cleaning the buildings and facilities; such written procedures shall be followed.
应制定书面程序，规定卫生职责范围，并充分详细地说明清洁厂房和设施所使用的清洁周期、方法、设备和物品；并按此程序执行。

(c) There shall be written procedures for use of suitable rodenticides, insecticides, fungicides, fumigating agents, and cleaning and sanitizing agents. Such written procedures shall be designed to prevent the contamination of equipment, components, drug product containers, closures, packaging, labeling materials, or drug products and shall be followed. Rodenticides, insecticides, and fungicides shall not be used unless registered and used in accordance with the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 135).
应制订关于使用适宜的灭鼠剂、杀虫剂、杀真菌剂、熏蒸剂、清洁消毒剂的书面操作规程。制订这些规程的目的是防止对设备、原辅料、药品容器、密封件、包装、标签材料或药品的污染，并按此程序执行。除《联邦杀虫剂、杀真菌剂及灭鼠剂法》（《美国法典》第7篇中第135节）登记和使用的品种外，其他的灭鼠剂、杀虫剂、杀真菌剂不得使用

(d) Sanitation procedures shall apply to work performed by contractors or temporary employees as well as work performed by full-time employees during the ordinary course of operations.
卫生程序适用于承包商或临时雇员从事的工作，以及全职雇员在正常作业过程中从事的工作。

211.58 Maintenance
维护

(a) Any building used in the manufacture, processing, packing, or holding of a drug product shall be

maintained in a good state of repair.

任何用于药品生产、加工、包装或贮存的厂房均应保持良好的修缮状态

Subpart D - Equipment
设备

211.63 Equipment design, size, and location
设备设计、尺寸和布局

(a) Equipment used in the manufacture, processing, packing, or holding of a drug product shall be of appropriate design, adequate size, and suitably located to facilitate operations for its intended use and for its cleaning and maintenance.

药品生产、加工、包装或贮存所使用的设备，应设计合理，大小适宜，布置合理，便于预定的使用和操作，并易于清洁和维护。

211.65 Equipment construction
设备结构

(a) Equipment shall be constructed so that surfaces that contact components, in-process materials, or drug products shall not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quality, or purity of the drug product beyond the official or other established requirements.

与各种原辅料、中间体或药品接触的设备表面，不得发生反应、析出或吸附作用，以免改变药品的安全性、鉴别、效价或含量、质量或纯度而超出官方或其他既定的要求。

(b) Any substances required for operation, such as lubricants or coolants, shall not come into contact with components, drug product containers, closures, in-process materials, or drug products so as to alter the safety, identity, strength, quality, or purity of the drug product beyond the official or other established requirements.

运行所需要的任何物质，诸如润滑剂、冷却剂，均不得与原辅料、药品容器、密封件、中间产品或药品接触，以免改变药品的安全性、鉴别、效价或含量、质量或纯度而超出官方或其他既定要求

211.67 Equipment cleaning and maintenance
设备的清洁和维护（2008年9月8日）

(a) Equipment and utensils shall be cleaned, maintained, and, as appropriate for the nature of the drug, sanitized and/or sterilized at appropriate intervals to prevent malfunctions or contamination that would alter the safety, identity, strength, quality, or purity of the drug product beyond the official or other established requirements.

设备和器具应周期性的清洁、维护，并根据药物的性质酌情进行消毒和/或灭菌，以防止故障或污染，从而改变药品的安全性、鉴别、效价或含量、质量或纯度，超出官方或其他既定要求。

(b) Written procedures shall be established and followed for cleaning and maintenance of equipment, including utensils, used in the manufacture, processing, packing, or holding of a drug product. These procedures shall include, but are not necessarily limited to, the following:

应建立并遵循关于药品生产、加工、包装或贮存所用设备（包括用具）的清洁和维护的操作规程。这些规程包括但不局限于，以下内容：

(1) Assignment of responsibility for cleaning and maintaining equipment;
分配设备清洁维护的责任。

(2) Maintenance and cleaning schedules, including, where appropriate, sanitizing schedules;
清洁和维护周期，适当时还应包括消毒周期。

(3) A description in sufficient detail of the methods, equipment, and materials used in cleaning and maintenance operations, and the methods of disassembling and reassembling equipment as necessary to assure proper cleaning and maintenance;
详细说明清洁维护操作所用的方法、设备和物品，以及必要的拆解和重新组装设备的方法，以确设备能进行适当的清洁和维护

(4) Removal or obliteration of previous batch identification;
去除或擦除上一批的标识

(5) Protection of clean equipment from contamination prior to use;
保护已清洁设备在使用前不受污染

(6) Inspection of equipment for cleanliness immediately before use.

设备使用前进行清洁检查

(c) Records shall be kept of maintenance, cleaning, sanitizing, and inspection as specified in §§ 211.180 and 211.182.

应按照第211.180条和第211.182条的规定保存维护、清洁、消毒和检查记录

[43 FR 45077, Sept. 29, 1978, as amended at 73 FR 51931, Sept. 8, 2008]

修订历史

1978年9月29日《美国联邦公报》43卷45077页

2008年9月8 日《美国联邦公报》73卷51931页

211.68 Automatic, mechanical, and electronic equipment
自动化、机械化和电子化设备（2008年9月8日）

(a) Automatic, mechanical, or electronic equipment or other types of equipment, including computers, or related systems that will perform a function satisfactorily, may be used in the manufacture, processing, packing, and holding of a drug product. If such equipment is so used, it shall be routinely calibrated, inspected, or checked according to a written program designed to assure proper performance. Written records of those calibration checks and inspections shall be maintained.

在药品生产、加工、包装和贮存的过程中，可以使用能够良好执行要求的自动化、机械化或电子设备，包括计算机或其它类型的设备。为保证此类设备工作性能良好，应根据书面规程对其进行周期性的校准、检查或核对。应保存校准和检查的记录

(b) Appropriate controls shall be exercised over computer or related systems to assure that changes in master production and control records or other records are instituted only by authorized personnel. Input to and output from the computer or related system of formulas or other records or data shall be checked for accuracy. The degree and frequency of input/output verification shall be based on the complexity and reliability of the computer or related system. A backup file of data entered into the computer or related system shall be maintained except where certain data, such as calculations performed in connection with laboratory analysis, are eliminated by computerization or other automated processes. In such instances a written record of the program shall be maintained along with appropriate validation data. Hard copy or alternative systems, such as duplicates, tapes, or microfilm, designed to assure that backup data are exact and complete and that it is secure from alteration, inadvertent erasures, or loss shall be maintained.

应对计算机或相关系统进行适当的控制，以确保主要生产数据和控制记录或其他记录的更改仅由授权人员进行。应检查计算机的相关公式系统或其他记录的数据输入和输出系统是否准确。输入/输出验证的程度和频率应基于计算机或相关系统的复杂性和可靠性。计算机或相关系统的数据应进行备份，除非某些数据（如与实验室分析相关的计算）通过计算机化或其他自动化程序消除。在这种情况下，应保留程序的书面记录以及适当的验证数据。硬拷贝或替代系统（如重复、磁带或缩微胶片）旨在确保备份数据准确且完整，并且安全免于被更改、无意擦除或丢失。

(c) Such automated equipment used for performance of operations addressed by §§ 211.101(c) or (d), 211.103, 211.182, or 211.188(b)(11) can satisfy the requirements included in those Sections relating to the performance of an operation by one person and checking by another person if such equipment is used in conformity with this Section, and one person checks that the equipment properly performed the operation.

用于211.101(c)或(d)、211.103、211.182、211.188(b)(11)所述规定操作的自动化设备，如果按本节要求使用，并有一人核实设备能够正确进行操作；则能够满足关于由一人操作、另一人复核的有关要求

[43 FR 45077, Sept. 29, 1978, as amended at 60 FR 4091, Jan. 20, 1995; 73 FR 51932, Sept. 8, 2008]

修订历史

1978年9月29日《美国联邦公报》43卷45077页

1995年1月20 日《美国联邦公报》60卷4091页

2008年9月8 日《美国联邦公报》73卷51932页

211.72 Filters
过滤器（2008年9月8日）

(a) Filters for liquid filtration used in the manufacture, processing, or packing of injectable drug products intended for human use shall not release fibers into such products. Fiber-releasing filters may be used when it is not possible to manufacture such products without the use of these filters. If use of a fiber-releasing filter is necessary, an additional nonfiber-releasing filter having a maximum nominal pore size rating of 0.2 micron

(0.45 micron if the manufacturing conditions so dictate) shall subsequently be used to reduce the content of Particles in the injectable drug product. The use of an asbestos-containing filter is prohibited.

人用注射药品的生产、加工或包装中，液体过滤使用的过滤器不得脱落纤维进入产品。当不使用脱落纤维的过滤器就不能生产此类药品时，可以使用这类过滤器。如果必须使用脱落纤维的过滤器，应随即使用最大标识孔径率为0.2μm（如生产条件指定可采用0.45μm）的无纤维脱落过滤器，以减少注射药品中的颗粒含量。禁止使用含石棉的过滤器。

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Subpart E - Control of Components and Drug Product Containers and Closures

原辅料、药品容器及密封件的管理

211.80 General requirements

一般要求

(a) There shall be written procedures describing in sufficient detail the receipt, identification, storage, handling, sampling, testing, and approval or rejection of components and drug product containers and closures; such written procedures shall be followed.

应有书面程序，充分详细说明原辅料和药品容器和密封件的接收、鉴别、贮存、处理、取样、检测、放行或拒手情况，并严格按照程序执行。

(b) Components and drug product containers and closures shall at all times be handled and stored in a manner to prevent contamination.

应以有效防止污染的方式处理及贮存原辅料、药品容器及密封件。

(c) Bagged or boxed components of drug product containers, or closures shall be stored off the floor and suitably spaced to permit cleaning and inspection.

药品容器或密封件的包装袋或包装箱，不能存放在地面，并进行适当的隔离，以便于清洁和检查。

(d) Each container or grouping of containers for components or drug product containers, or closures shall be identified with a distinctive code for each lot in each shipment received. This code shall be used in recording the disposition of each lot. Each lot shall be appropriately identified as to its status (i.e., quarantined, approved, or rejected).

对于每次运输到货的每批次的原辅料、药品容器或密封件的每个容器或容器组，应该用不同的代码进行标识。这一代码应用于记录每批的处理信息。每批状态应该适当标示状态（如：待验、合格或不合格

211.82 Receipt and storage of untested components, drug product containers, and closures

未经检验的原辅料、药品容器和密封件的接收和存贮（2008年9月8日）

(a) Upon receipt and before acceptance, each container or grouping of containers of components, drug product containers, and closures shall be examined visually for appropriate labeling as to contents, container damage or broken seals, and contamination.

收到和验收前，应对每个集装箱或集装箱的部件、药品容器和封口进行目视检查，以便对内容、容器损坏或密封件损坏以及污染进行适当的标记。

在接收物料前，应对原辅料、药品容器或密封件的每个或每组容器进行目视检查，以确定是否有适当的标签，是否有容器损坏或密封破损，以及污染情况。

(b) Components, drug product containers, and closures shall be stored under quarantine until they have been tested or examined, whichever is appropriate, and released. Storage within the area shall conform to the requirements of § 211.80.

原辅料、药品容器或密封件在完成适当的检查或检验直至放行前应存放在待验区。仓储区域应符合§211.80 的要求

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211.84 Testing and approval or rejection of components, drug product containers, and closures

原辅料、药品容器及密封件的检验、批准或拒收（2008年9月8日）

(a) Each lot of components, drug product containers, and closures shall be withheld from use until the lot has been sampled, tested, or examined, as appropriate, and released for use by the quality control unit.

每批原辅料、药品容器和密封件，在质量管理部门完成适当的取样、检验或检查及放行使用前，应限制使用。

(b) Representative samples of each shipment of each lot shall be collected for testing or examination. The number of containers to be sampled, and the amount of material to be taken from each container, shall be based upon appropriate criteria such as statistical criteria for component variability, confidence levels, and degree of precision desired, the past quality history of the supplier, and the quantity needed for analysis and reserve where required by § 211.170.

应对每批运输到货的物料取样，取样应具代表性，样品用于检验或检查。应有适当的标准来确定容器抽样数和每个容器的取样量，例如：原辅料可变性的统计学标准、可信度、预期精确程度、供应商的过去的质量历史、277.170要求的分析需用量及留样量。

(c) Samples shall be collected in accordance with the following procedures:

样品应按照下列程序取样

(1) The containers of components selected shall be cleaned when necessary in a manner to prevent introduction of contaminants into the component.

必要时，应对所选原辅料的容器进行清洁，以防止污染物进入原辅料。

(2) The containers shall be opened, sampled, and resealed in a manner designed to prevent contamination of their contents and contamination of other components, drug product containers, or closures.

包装容器的开启、取样和重新封口方式应能够防止内容物被污染，且不能对其它原辅料、药品容器或密封件造成污染。

(3) Sterile equipment and aseptic sampling techniques shall be used when necessary.

必要时应当使用无菌设备和无菌取样技术

(4) If it is necessary to sample a component from the top, middle, and bottom of its container, such sample subdivisions shall not be composited for testing.

如果需要从容器顶部、中间和底部取样的，不得将分样混合后进行检测

(5) Sample containers shall be identified so that the following information can be determined: name of the material sampled, the lot number, the container from which the sample was taken, the date on which the sample was taken, and the name of the person who collected the sample.

样品容器应有标识，以便确认如下样品信息：所取物料名称、批号、被取容器、取样日期及样品采集人姓名

(6) Containers from which samples have been taken shall be marked to show that samples have been removed from them.

被取样的包装容器应做标记，表明其样品已取。

(d) Samples shall be examined and tested as follows:

样品应按以下方式进行检查和检验：

(1) At least one test shall be conducted to verify the identity of each component of a drug product. Specific identity tests, if they exist, shall be used.

至少应进行一项测试，以确认药品中每种成分的身份。如果存在特定的身份测试，则应使用。

(2) Each component shall be tested for conformity with all appropriate written specifications for purity, strength, and quality. In lieu of such testing by the manufacturer, a report of analysis may be accepted from the supplier of a component, provided that at least one specific identity test is conducted on such component by the manufacturer, and provided that the manufacturer establishes the reliability of the supplier's analyses through appropriate validation of the supplier's test results at appropriate intervals.

每一原辅料都应按照适当的操作规程或标准测试其纯度、含量（或效价）和质量。若生产商对供应商进行了适当的定期审计，确认供应商分析方法可靠，则供应商的原辅料分析报告书可以代替生产商的此类检测。但生产商对某一原辅料的鉴别试验不能取消。

(3) Containers and closures shall be tested for conformity with all appropriate written specifications. In lieu of such testing by the manufacturer, a certificate of testing may be accepted from the supplier, provided that at least a visual identification is conducted on such containers/closures by the manufacturer and provided that the manufacturer establishes the reliability of the supplier's test results through appropriate validation of the supplier's test results at appropriate intervals.

每一容器和密封件都应按照适当的操作规程或标准进行测试。若生产商对供应商进行了适当的定期审计，确认供应商分析方法可靠，则供应商的容器和密封件分析报告书可以代替生产商的此类检测。但制造商须至少对该容器和密封件进行目视检查。

(4) When appropriate, components shall be microscopically examined.
必要时，应在显微镜下对原辅料进行检查。

(5) Each lot of a component, drug product container, or closure that is liable to contamination with filth, insect infestation, or other extraneous adulterant shall be examined against established specifications for such contamination.
对容易受到污秽、虫害或其他外来挠杂物污染的原辅料、药品容器或密封件，应按照既定的质量标准对其污染情况进行检验。

(6) Each lot of a component, drug product container, or closure with potential for microbiological contamination that is objectionable in view of its intended use shall be subjected to microbiological tests before use.
对于可能受到微生物污染从而不利于其预定用途的原辅料、药品容器或密封件，在使用前每批均应进行微生物学检验。

(e) Any lot of components, drug product containers, or closures that meets the appropriate written specifications of identity, strength, quality, and purity and related tests under Paragraph (d) of this Section may be approved and released for use. Any lot of such material that does not meet such specifications shall be rejected.
符合相关的鉴别、含量（效价）、质量和纯度的书面质量标准以及本节 (d) 段的相关检验要求的原辅料、药品容器或密封件均可批准和放行使用。任何不符合上述质量标准要求的物料均判定为不合格。

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211.86 Use of approved components, drug product containers, and closures
放行后原辅料、药品容器及密封件的使用

Components, drug product containers, and closures approved for use shall be rotated so that the oldest approved stock is used first. Deviation from this requirement is permitted if such deviation is temporary and appropriate.
应按顺序使用放行后的的原辅料、药品容器和密封件，以便首先使用最先入库的物料。允许在零时或适当的情况下偏离。

211.87 Retesting of approved components, drug product containers, and closures
放行后原辅料、药品容器及密封件的复检

Components, drug product containers, and closures shall be retested or reexamined, as appropriate, for identity, strength, quality, and purity and approved or rejected by the quality control unit in accordance with § 211.84 as necessary, e.g., after storage for long periods or after exposure to air, heat or other conditions that might adversely affect the component, drug product container, or closure.
在必要时（如：长时间贮存后或曝露在空气、高温或其它可能对原辅料，药品容器，密封件有不利影响的条件），应根据 Sec. 211.84 的要求，对原辅料、药品容器和密封件的鉴别、含量（效价）、质量和纯度进行适当的复验或复查，并由质量管理部门批准或拒收

211.89 Rejected components, drug product containers, and closures
不合格原辅料、药品容器及密封件

Rejected components, drug product containers, and closures shall be identified and controlled under a quarantine system designed to prevent their use in manufacturing or processing operations for which they are unsuitable.
不合格的原辅料、药品容器及密封件应有标识并在隔离区进行贮存，防止它们用于生产或加工操作。

211.94 Drug product containers and closures

药品容器和密封件（2016年11月18日）

(a) Drug product containers and closures shall not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quality, or purity of the drug beyond the official or established requirements.

药品容器及密封件应不发生反应、析出或吸附作用，以免改变药品的安全性、鉴别、含量（效价）、质量或纯度而超出官方或其他既定要求

(b) Container closure systems shall provide adequate protection against foreseeable external factors in storage and use that can cause deterioration or contamination of the drug product.

容器密封系统应提供充分的保护，防止在贮存和使用中出现可能导致药物产品变质或污染的可预见外部因素。

(c) Drug product containers and closures shall be clean and, where indicated by the nature of the drug, sterilized and processed to remove pyrogenic properties to assure that they are suitable for their intended use. Such depyrogenation processes shall be validated.

药品容器和密封件应洁净，并根据药物性质需要进行灭菌和除热原，保证其适用于预期用途。除热原工艺应经过验证。

(d) Standards or specifications, methods of testing, and, where indicated, methods of cleaning, sterilizing, and processing to remove pyrogenic properties shall be written and followed for drug product containers and closures.

应制订并遵循药品容器和密封件的标准或质量标准、检验方法以及必要时的清洁，灭菌和除热原方法的书面规程

(e) Medical gas containers and closures must meet the following requirements –

医用气体容器和密封件必须符合以下要求

(1) Gas-specific use outlet connections. Portable cryogenic medical gas containers that are not manufactured with permanent gas use outlet connections (e.g., those that have been silver-brazed) must have gas-specific use outlet connections that are attached to the valve body so that they cannot be readily removed or replaced (without making the valve inoperable and preventing the containers' use) except by the manufacturer. For the purposes of this Paragraph , the term “manufacturer” includes any individual or firm that fills high-pressure medical gas cylinders or cryogenic medical gas containers. For the purposes of this Section, a “portable cryogenic medical gas container” is one that is capable of being transported and is intended to be attached to a medical gas supply system within a hospital, health care entity, nursing home, other facility, or home health care setting, or is a base unit used to fill small cryogenic gas containers for use by individual patients. The term does not include cryogenic containers that are not designed to be connected to a medical gas supply system, e.g., tank trucks, trailers, rail cars, or small cryogenic gas containers for use by individual patients (including portable liquid oxygen units as defined at § 868.5655 of this Chapter).

气体专用出口接头，未采用永久性气体专用出口接头制造（例如，采用熔银焊接的接头）的便携式低温医用气体容器，必须具备与阀身相连的气体专用接头，使得它们不能轻易地被制造商以外的人员移除或更换（但并不导致阀门和容器无法使用）。本段中，“制造商”一词包括灌装高压医用气瓶或低温医用气体容器的任何个人或企业。本节中，“便携式低温医用气体容器”是指能够被运输并且旨在连接到医院、保健院、疗养院、其他设施或家庭保健设施的医用气体供应系统，或是用于灌装供个别患者适用的小型低温气体容器的基本单元。该术语不包括并非用来连接到医疗气体供应系统的低温容器，例如罐车，拖车，轨道车或供个别患者使用的小型低温气体容器（包括本章第 868.5655 段定义的便携式液氧单位）。

(2) (2) Label and coloring requirements. The labeling specified at § 201.328(a) of this Chapter must be affixed to the container in a manner that does not interfere with other labeling and such that it is not susceptible to becoming worn or inadvertently detached during normal use. Each such label as well as materials used for coloring medical gas containers must be reasonably resistant to fading, durable when exposed to atmospheric conditions, and not readily soluble in water.

标签和着色要求。本章第 201.328(a)条规定的标签必须以不干扰其他标签的方式固定在容器上，并且在正常使用时不易磨损或无意中脱落。每个这样的标签以及用于着色医用气体容器的材料必须在暴露于大气条件下时具有合理的抗褪色性，耐久性，并且不易溶于水。

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Subpart F - Production and Process Controls
生产和工艺控制

211.100 Written procedures; deviations
书面程序及偏离

(a) There shall be written procedures for production and process control designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess. Such procedures shall include all requirements in this Subpart. These written procedures, including any changes, shall be drafted, reviewed, and approved by the appropriate organizational units and reviewed and approved by the quality control unit.

应制订生产和工艺控制的书面规程，以保证药品具有所声称的或标明拥有的鉴别、规格、质量和纯度。此类规程应包括该子部分中所有要求。这些书面规程（包括任何变更）应由相应的部门起草、审核和批准，并由质量管理部门进行审核和批准。

(b) (b) Written production and process control procedures shall be followed in the execution of the various production and process control functions and shall be documented at the time of performance. Any deviation from the written procedures shall be recorded and justified.

在进行不同的生产和工艺控制职能时应遵守制订的生产和工艺控制规程，并于当场做好记录。任何偏离书面规程的偏差都应予以记录并作出合理解释

211.101 Charge-in of components
原辅料的投料（2008年9月8日）

Written production and control procedures shall include the following, which are designed to assure that the drug products produced have the identity, strength, quality, and purity they purport or are represented to possess:

生产和工艺控制书面规程应包括以下方面，以保证生产的药品具有所声称的或标明拥有的鉴别、规格、质量和纯度：

(a) The batch shall be formulated with the intent to provide not less than 100 percent of the labeled or established amount of active ingredient.

配制该批要时，活性成分的投料量应不少于标示量或既定量的100%

(b) Components for drug product manufacturing shall be weighed, measured, or subdivided as appropriate. If a component is removed from the original container to another, the new container shall be identified with the following information:

用于药品制造的原辅料应适当地称重，测量或分装。如果将一个原辅料从原始容器中移到另一个容器中，则应使用以下信息来标识新容器：

(1) Component name or item code;
原辅料名称或物料代码

(2) Receiving or control number;
接收或者控制号码（批号）

(3) Weight or measure in new container;
新容器的重量或者计量

(4) Batch for which component was dispensed, including its product name, strength, and lot number.
用于生产产品的信息，包括产品名称、规格和批号。

(c) Weighing, measuring, or subdividing operations for components shall be adequately supervised. Each container of component dispensed to manufacturing shall be examined by a second person to assure that:

原辅料的称量、计量或分装操作应受到充分的监督。每个分发至生产的原辅料容器应由第二人检查，以确保：

(1) The component was released by the quality control unit.
该原辅料已由质量控制部门放行。

(2) The weight or measure is correct as stated in the batch production records.
称量或计量与批生产记录中声明的数量一致。

(3) The containers are properly identified. If the weighing, measuring, or subdividing operations are performed by automated equipment under § 211.68, only one person is needed to assure Paragraph s (c)(1), (c)(2), and (c)(3) of this Section.
容器经过适当标识。如果采用 211.68 涉及的自动化装备执行称量、计量或再分操作，只需要一个人确保本节(c)(1)，(c)(2)，和(c)(3)段的要求。

(d) Each component shall either be added to the batch by one person and verified by a second person or, if

the components are added by automated equipment under § 211.68, only verified by one person.

每一原辅料的投料都应由一人操作，第二人复核。如果采用 211.68 涉及的自动化设备进行添加，只需要一个人复核。

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211.103 Calculation of yield

收率计算（2008年9月8日）

ctual yields and percentages of theoretical yield shall be determined at the conclusion of each appropriate phase of manufacturing, processing, packaging, or holding of the drug product. Such calculations shall either be performed by one person and independently verified by a second person, or, if the yield is calculated by automated equipment under § 211.68, be independently verified by one person.

在药品生产，加工，包装或贮存中，应在每一个适当阶段结束的时，确定实际产量和理论产量的比值（收率）。此类计算应由一人进行，并由第二人进行独立复核，如果采用 211.68 涉及的自动化设备进行产量计算时，仅需一人独立核实

[73 FR 51932, Sept. 8, 2008]

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211.105 Equipment identification

设备标识

(a) All compounding and storage containers, processing lines, and major equipment used during the production of a batch of a drug product shall be properly identified at all times to indicate their contents and, when necessary, the phase of processing of the batch.

药品的每批生产中所使用的全部配料和贮存容器、生产线以及主要设备均应进行适当的标识，标明内容物，必要时还应标明该批的加工阶段。

(b) Major equipment shall be identified by a distinctive identification number or code that shall be recorded in the batch production record to show the specific equipment used in the manufacture of each batch of a drug product. In cases where only one of a Particular type of equipment exists in a manufacturing facility, the name of the equipment may be used in lieu of a distinctive identification number or code.

主要设备应使用不同的识别编号或代码进行标识，并将其记录在批生产记录中，以体现每批药品生产所使用的准确设备。在生产设施中只存在一台一种型号的设备的情况下（同名称的设备只有一台），可以使用设备名称以取代识别编号或代码

211.110 Sampling and testing of in-process materials and drug products

中间产品及药品的取样和检验（2008年9月8日）

(a) To assure batch uniformity and integrity of drug products, written procedures shall be established and followed that describe the in-process controls, and tests, or examinations to be conducted on appropriate samples of in-process materials of each batch. Such control procedures shall be established to monitor the output and to validate the performance of those manufacturing processes that may be responsible for causing variability in the characteristics of in-process material and the drug product. Such control procedures shall include, but are not limited to, the following, where appropriate:

为确保药品每个批次的均一性和稳定性，应建立书面程序并遵循它进行生产，书面程序应描述对每批次对中间产品的过程控制，检测或检查，监控产出，并确认可能导致生产过程中中间产品和药品特性发生变化的控制工艺。此类控制程序应包括但不限于以下内容:

(1) Tablet or capsule weight variation;

片剂或胶囊剂的重量变化。

(2) Disintegration time;

崩解时间

(3) Adequacy of mixing to assure uniformity and homogeneity;

充分混合，保证均匀一性和重现性

(4) Dissolution time and rate;

溶出时间和速率。

(5) Clarity, completeness, or pH of solutions.

溶液的澄清度，溶解完成度或pH值。

(6) Bioburden testing.

生物负荷检测

(b) Valid in-process specifications for such characteristics shall be consistent with drug product final specifications and shall be derived from previous acceptable process average and process variability estimates where possible and determined by the application of suitable statistical procedures where appropriate. Examination and testing of samples shall assure that the drug product and in-process material conform to specifications.

这些性状的中控质量标准应与药品的最终质量标准一致，而且可能的话应来源于以前的可接受的平均值和工艺变量评估，在适当情况下可通过应用适当的统计程序来确定，样品的检查和检验应保证药品和中间产品符合质量标准。

(c) In-process materials shall be tested for identity, strength, quality, and purity as appropriate, and approved or rejected by the quality control unit, during the production process, e.g., at commencement or completion of significant phases or after storage for long periods.

加工材料应酌情进行身份、强度、质量和纯度测试，并在生产过程中（例如在重要阶段开始或完成或贮存后）获得质量控制部门的批准或拒绝

在生产过程中（如重要阶段的开始或结束时，或长时间贮存后），应适当对中间产品的鉴别、规格、质量和纯度进行检验，由质量管理部门批准或拒收。

(d) Rejected in-process materials shall be identified and controlled under a quarantine system designed to prevent their use in manufacturing or processing operations for which they are unsuitable.

被拒绝的加工材料应在检疫制度下进行识别和控制，以防止其用于不适合的制造或加工作业

不合格的中间产品应做好标识，并按要求进行隔离存放，以防止其用于生产或加工操作。

[43 FR 45077, Sept. 29, 1978, as amended at 73 FR 51932, Sept. 8, 2008]

修订历史

1978年9月29日《美国联邦公报》43卷45077页

2008年9月8 日《美国联邦公报》73卷51932页

211.111 Time limitations on production

生产时间控制

(a) When appropriate, time limits for the completion of each phase of production shall be established to assure the quality of the drug product. Deviation from established time limits may be acceptable if such deviation does not compromise the quality of the drug product. Such deviation shall be justified and documented.

在适当情况下，应对生产的每一阶段设定时限，以确保药品的质量。在不影响药品质量的前提下，设定时限允一定的偏离。但此类偏差应予以合理解释并记录。

211.113 Control of microbiological contamination

微生物污染控制（2008年9月8日）

(a) Appropriate written procedures, designed to prevent objectionable microorganisms in drug products not required to be sterile, shall be established and followed.

应建立并遵循适当的书面程序，用于防止非无菌产品被有害微生物污染。

(b) Appropriate written procedures, designed to prevent microbiological contamination of drug products purporting to be sterile, shall be established and followed. Such procedures shall include validation of all aseptic and sterilization processes.

应建立和遵循适当的书面程序，以防止无菌产品的微生物污染。此类程序应包括灭菌和无菌工艺验证。

[43 FR 45077, Sept. 29, 1978, as amended at 73 FR 51932, Sept. 8, 2008]

修订历史

1978年9月29日《美国联邦公报》43卷45077页

211.115 Reprocessing.

返工

(a) Written procedures shall be established and followed prescribing a system for reprocessing batches that do not conform to standards or specifications and the steps to be taken to insure that the reprocessed batches will conform with all established standards, specifications, and characteristics.

应当建立书面程序，并遵循规定不符合标准或规格的后处理批次制度，并采取措施确保后处理批次符合所有既定标准、规格和特点。

应制订并遵循书面规程，规定不符合标准或质量标准的批次进行返工以及为确保返工后批次符合所有既定标准，质量标准和特性而采取的工序。

(b) Reprocessing shall not be performed without the review and approval of the quality control unit.

未经质检部门审核和批准，不得进行返工。

Subpart G - Packaging and Labeling Control

包装和标签管理

211.122 Materials examination and usage criteria

物料检查和使用标准（2012年3月20日）

(a) There shall be written procedures describing in sufficient detail the receipt, identification, storage, handling, sampling, examination, and/or testing of labeling and packaging materials; such written procedures shall be followed. Labeling and packaging materials shall be representatively sampled, and examined or tested upon receipt and before use in packaging or labeling of a drug product.

应制订并遵循足够详细地描述标签和包装材料的接收、鉴别、贮存、操作、取样、检查和/或检验的书面规程。在药品包装或贴签前，应对标签和包装材料进行取样检查或检验，取样应具有代表性。

(b) Any labeling or packaging materials meeting appropriate written specifications may be approved and released for use. Any labeling or packaging materials that do not meet such specifications shall be rejected to prevent their use in operations for which they are unsuitable.

符合适当书面质量标准的标签或包装材料可以批准放行使用。对于任何不符合此类质量标准的标签或包装材料应予以拒收，并防止其用于并不适用的操作。

(c) Records shall be maintained for each shipment received of each different labeling and packaging material indicating receipt, examination or testing, and whether accepted or rejected.

对于每次到货的每一批不同标签和包装材料均应做接收、检查或检验以及接受或拒收的记录并加以保存。

(d) Labels and other labeling materials for each different drug product, strength, dosage form, or quantity of contents shall be stored separately with suitable identification. Access to the storage area shall be limited to authorized personnel.

用于每一不同药品、规格、剂型或内容数量的标签和其它标签物，应分开存放，并适当标识。仓储区仅限授权人员进入。

(e) Obsolete and outdated labels, labeling, and other packaging materials shall be destroyed.

废弃或过期的标签、标签材料和其它包装材料应予销毁。

(f) Use of gang-printed labeling for different drug products, or different strengths or net contents of the same drug product, is prohibited unless the labeling from gang-printed sheets is adequately differentiated by size, shape, or color.

禁止对不同药品或相同药品的不同规格或装量进行标签的联合印刷（同时打印），除非组合印刷纸张的标签在尺寸、形状或颜色上能足以区分。

(g) If cut labeling is used for immediate container labels, individual unit cartons, or multiunit cartons containing immediate containers that are not packaged in individual unit cartons, packaging and labeling operations shall include one of the following special control procedures:

如果将切割试标签用于产品容器标签，小盒或没有装盒直接装箱的纸箱，则包装和贴标签操作应应至少包括以下特殊控制措施之一：

(1) Dedication of labeling and packaging lines to each different strength of each different drug product;

不同品种或不同规格的药品的贴标和包装专线生产。

(2) Use of appropriate electronic or electromechanical equipment to conduct a 100-percent examination for correct labeling during or after completion of finishing operations; or

用适当的电子或电子机械设备在生产过程中或完成后对标签的正确性进行100%的检查；或

(3) Use of visual inspection to conduct a 100-percent examination for correct labeling during or after completion of finishing operations for hand-applied labeling. Such examination shall be performed by one person and independently verified by a second person.

对于手工贴标，在操作过程中或完成后对正确贴签进行100%目视检查。此项检查应由一人进行，另一人独立复核。

(4) Use of any automated technique, including differentiation by labeling size and shape, that physically prevents incorrect labeling from being processed by labeling and packaging equipment.

使用自动化技术，包括区分标签尺寸和形状，以防止贴签和包装设备操作贴错标签。

(h) Printing devices on, or associated with, manufacturing lines used to imprint labeling upon the drug product unit label or case shall be monitored to assure that all imprinting conforms to the print specified in the batch production record.

安置在生产线上的或与之联用的在产品容器标签或箱子上打印的设备应受到相应的监控，以保证所有的打印与批生产记录中确定的内容一致。

[43 FR 45077, Sept. 29, 1978, as amended at 58 FR 41353, Aug. 3, 1993; 77 FR 16163, Mar. 20, 2012]
77 FR 16163，2012年3月20日]

修订历史

1978年9月29日《美国联邦公报》43卷45077页
1993年8月3日《美国联邦公报》58卷41353页
2012年3月20日《美国联邦公报》77卷16163页

211.125 Labeling issuance
标签的发放（2016年11月18日）

(a) Strict control shall be exercised over labeling issued for use in drug product labeling operations.

在药品贴签操作中应对标签的发放和使用进行严格的控制

(b) Labeling materials issued for a batch shall be carefully examined for identity and conformity to the labeling specified in the master or batch production records.

发放的每批所用标签材料应被细致检查加以鉴别，并确认是否与母版或批生产记录中规定的一致。

(c) Procedures shall be used to reconcile the quantities of labeling issued, used, and returned, and shall require evaluation of discrepancies found between the quantity of drug product finished and the quantity of labeling issued when such discrepancies are outside narrow preset limits based on historical operating data. Such discrepancies shall be investigated in accordance with § 211.192. Labeling reconciliation is waived for cut or roll labeling if a 100-percent examination for correct labeling is performed in accordance with § 211.122(g)(2). Labeling reconciliation is also waived for 360° wraparound labels on portable cryogenic medical gas containers.

应用程序对标签的发放量、使用量、退回量的物料平衡计算，当药品成品数量和标签发放数量间的差异超出基于历史操作数据预定的限度时，应对出现的差异进行评估。此类差异应按照 Sec. 211.192 的要求展开调查。如果按照 Sec. 211.122(g)(2)进行了100%正确贴签检查，则对于切割标签或滚卷标签免于标签的物料平衡计算。便携式低温医用气体容器的 360°环绕标签，也可以免于标签的物料平衡计算。

(d) All excess labeling bearing lot or control numbers shall be destroyed.

所有印有批号或控制号的剩余标签应予销毁。

(e) Returned labeling shall be maintained and stored in a manner to prevent mixups and provide proper identification.

退回的标签应做好标识和进行适当保存以防止混淆。

(f) Procedures shall be written describing in sufficient detail the control procedures employed for the issuance of labeling; such written procedures shall be followed.

应制订并遵循关于详细描述标签发放和使用的控制程序的书面规程。

[43 FR 45077, Sept. 29, 1978, as amended at 58 FR 41354, Aug. 3, 1993; 81 FR 81697, Nov. 18, 2016]

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1978年9月29日《美国联邦公报》43卷45077页
1993年8月3日《美国联邦公报》58卷41354页
2016年11月18日《美国联邦公报》81卷81697页

211.130 Packaging and labeling operations
包装及贴签操作（1993年8月3日）

There shall be written procedures designed to assure that correct labels, labeling, and packaging materials are used for drug products; such written procedures shall be followed. These procedures shall incorporate the following features:

应制订并遵循相关的书面规程，以确保正确的标签、标签材料和其它包装材料用于药品。这些规程应具备以下特别要求

(a) (a) Prevention of mixups and cross-contamination by physical or spatial separation from operations on other drug products.

不同品种或规格同时生产时应进行物理或空间上的隔离，以防止混淆和交叉污染

(b) (b) Identification and handling of filled drug product containers that are set aside and held in unlabeled condition for future labeling operations to preclude mislabeling of individual containers, lots, or portions of lots. Identification need not be applied to each individual container but shall be sufficient to determine name, strength, quantity of contents, and lot or control number of each container.

已完成生产单未贴签的产品容器应进行标识和控制，防止单个容器、批或批的一部分发生混淆导致贴标错误，不需对每一单个容器进行标识，但应能足以确定每个容器的物料名称、规格、内容物装量和批号或控制号

(c) (c) Identification of the drug product with a lot or control number that permits determination of the history of the manufacture and control of the batch.

对具有批号或控制号药品进行鉴别确认证明该批的生产和控制历史。

(d) (d) Examination of packaging and labeling materials for suitability and correctness before packaging operations, and documentation of such examination in the batch production record.

在包装操作前，对包装及标签材料的适合性和正确性进行检查，并将检查情况记入批生产记录中。

(e) (e) Inspection of the packaging and labeling facilities immediately before use to assure that all drug products have been removed from previous operations. Inspection shall also be made to assure that packaging and labeling materials not suitable for subsequent operations have been removed. Results of inspection shall be documented in the batch production records.

包装或贴签设施在使用前应进行检查，保证上次操作的所有药品已被清走。还应检查确保不适于随后操作的包材和标签已经清走。检查结果应记录在批生产记录中。

[43 FR 45077, Sept. 29, 1978, as amended at 58 FR 41354, Aug. 3, 1993]

修订历史

1978年9月29日《美国联邦公报》43卷45077页

1993年8月3 日《美国联邦公报》58卷41354页

211.132 Tamper-evident packaging requirements for over-the-counter (OTC) human drug products
人用药品非处方药（OTC）的防伪包装要求（1998年11月4日）

(a) General.

通用要求

The Food and Drug Administration has the authority under the Federal Food, Drug, and Cosmetic Act (the act) to establish a uniform national requirement for tamper-evident packaging of OTC drug products that will improve the security of OTC drug packaging and help assure the safety and effectiveness of OTC drug products. An OTC drug product (except a dermatological, dentifrice, insulin, or lozenge product) for retail sale that is not packaged in a tamper-resistant package or that is not properly labeled under this Section is adulterated under Section 501 of the act or misbranded under Section 502 of the act, or both.

根据《联邦食品、药品和化妆品法案》（《法案》），食品药品管理局有权对 OTC 药品防伪包装制订统一的国家要求，以提高 OTC 药品包装的安全性，有助于保证 OTC 药品的安全性和有效性。零售的 OTC 药品（皮肤科、牙齿清洁、胰岛素或喉锭产品除外），如未按本节要求采用防伪包装或缺乏适宜标签，则根据《法案》第 501 节判定为掺假，或根据《法案》第 502 节判定为误标，或二者均是。

(b) Requirements for tamper-evident package.

防伪包装的要求

(1) Each manufacturer and packer who packages an OTC drug product (except a dermatological, dentifrice, insulin, or lozenge product) for retail sale shall package the product in a tamper-evident package, if this product is accessible to the public while held for sale. A tamper-evident package is one having one or more indicators or barriers to entry which, if breached or missing, can reasonably be expected to provide visible evidence to consumers that tampering has occurred. To reduce the

likelihood of successful tampering and to increase the likelihood that consumers will discover if a product has been tampered with, the package is required to be distinctive by design or by the use of one or more indicators or barriers to entry that employ an identifying characteristic (e.g., a pattern, name, registered trademark, logo, or picture). For purposes of this Section, the term "distinctive by design" means the packaging cannot be duplicated with commonly available materials or through commonly available processes. A tamper-evident package may involve an immediate-container and closure system or secondary-container or carton system or any combination of systems intended to provide a visual indication of package integrity. The tamper-evident feature shall be designed to and shall remain intact when handled in a reasonable manner during manufacture, distribution, and retail display.

如果产品在出售时公众易于购买，那么该类用于零售的 OTC 药品（皮肤科、牙齿清洁、胰岛素或喉锭类产品除外）的生产商和包装商应采用防伪包装，防伪包装是指包装在入口处设置一种或多种指示装置或屏障，如果破坏或丢失，则有理由认为是向消费者提供的明显证据，表明商品已经发生了破损。为了减少成功损坏的可能性并提高消费者发现已损坏产品的可能性，包装应采用特殊的设计或使用鉴别性特征（如：图案、名称、注册商标、徽标或图片）在入口处设置一种或多种指示装置或屏障。基于本节目的，术语"特殊的设计"是指包装不能用普通易得的材料或通过普通易得的工艺进行复制。为了提供可目视的包装完整性指示，防伪包装可以包括内包装和密封系统或外包装或纸盒系统或任何系统的组合。显损特征应进行合理设计，并且在生产、发运和零售摆放过程中，经合理方式操作后仍能保持完整无缺。

(2) In addition to the tamper-evident packaging feature described in Paragraph (b)(1) of this Section, any two-piece, hard gelatin capsule covered by this Section must be sealed using an acceptable tamper-evident technology.

除本节(b)(1)描述过的防伪包装特点以外，本部分涵盖的任何两瓣式硬胶囊都必须使用可接受的防伪技术进行密封。

(c) Labeling.

标签。

(1) In order to alert consumers to the specific tamper-evident feature(s) used, each retail package of an OTC drug product covered by this Section (except ammonia inhalant in crushable glass ampules, containers of compressed medical oxygen, or aerosol products that depend upon the power of a liquefied or compressed gas to expel the contents from the container) is required to bear a statement that:

为提醒消费者有关使用的特殊防伪特性，本节所包括的 OTC 药品（除易折玻璃安瓿装氨吸入剂、医疗用压缩氧气的容器或利用液化或压缩气体将内容物从容器内排出的气雾剂产品外）的每一零售包装均要求在显著位置标注声明如下

(i) Identifies all tamper-evident feature(s) and any capsule sealing technologies used to comply with Paragraph (b) of this Section;

指明所有符合本节(b)部分的防伪包装特点以及胶囊密封技术

(ii) Is prominently placed on the package; and

置于包装的显著位置

(iii) Is so placed that it will be unaffected if the tamper-evident feature of the package is breached or missing.

位置合适，当防伪包装特点破损或丢失时不会受到影响

(2) If the tamper-evident feature chosen to meet the requirements in Paragraph (b) of this Section uses an identifying characteristic, that characteristic is required to be referred to in the labeling statement. For example, the labeling statement on a bottle with a shrink band could say "For your protection, this bottle has an imprinted seal around the neck."

如选用符合本节(b)部分要求的防伪特征作为鉴别用的特征，该特征应在标签声明中提及。例如，使用收缩领圈瓶子的标签声明中可以写道："为给您提供保护，此瓶在颈部有一刻印封条"

(d) Request for exemptions from packaging and labeling requirements. A manufacturer or packer may request an exemption from the packaging and labeling requirements of this Section. A request for an exemption is required to be submitted in the form of a citizen petition under § 10.30 of this Chapter and should be clearly identified on the envelope as a "Request for Exemption from the Tamper-Evident Packaging Rule." The petition is required to contain the following:

包装和标签要求的豁免申请。生产商或包装商可以申请本节包装和标签要求的豁免。按照本章 Sec.10.30中的要求，以公民申请表的形式提交豁免申请，并在信封上清楚注明"防伪包装条款的豁免申请"。申请书应包括以下内容

(1) The name of the drug product or, if the petition seeks an exemption for a drug class, the name of the drug class, and a list of products within that class.
药品名称，如果对某一类药寻求豁免，则为药类名称及该类药的产品列表。

(2) The reasons that the drug product's compliance with the tamper-evident packaging or labeling requirements of this Section is unnecessary or cannot be achieved.
说明药品没有必要符合或无法达到本节防伪包装或标签的要求的原因。

(3) A description of alternative steps that are available, or that the petitioner has already taken, to reduce the likelihood that the product or drug class will be the subject of malicious adulteration.
可供选择的或申请人已采用的降低产品或药品类别恶意掺假的可能性的措施的描述。

(4) Other information justifying an exemption.
其它支持豁免的信息。

(e) OTC drug products subject to approved new drug applications. Holders of approved new drug applications for OTC drug products are required under § 314.70 of this Chapter to provide the agency with notification of changes in packaging and labeling to comply with the requirements of this Section. Changes in packaging and labeling required by this regulation may be made before FDA approval, as provided under § 314.70(c) of this Chapter. Manufacturing changes by which capsules are to be sealed require prior FDA approval under § 314.70(b) of this Chapter.

属于已批准新药申请的 OTC 药品申请 OTC 药品的已批准新药申请的持有人，根据本章 Sec. 314.70， 需要向申请机构提供符合本节要求的包装和标签的变更通知。根据本章 Sec. 314.70(c)要求，可以在 FDA 批准前根据本法规的要求进行包装和标签变更。根据本章 Sec. 314.70(b)的要求，密封胶囊所用的生产变更要求具备 FDA 事先批准

(f) Poison Prevention Packaging Act of 1970. This Section does not affect any requirements for "special packaging" as defined under § 310.3(l) of this Chapter and required under the Poison Prevention Packaging Act of 1970.

《1970 年防毒包装法案》 本节不影响本章§310.3(l)中定义的"特殊包装"及《1970 年防毒包装法案》的任何要求。

(Approved by the Office of Management and Budget under OMB control number 0910-0149) [54 FR 5228, Feb. 2, 1989, as amended at 63 FR 59470, Nov. 4, 1998]
（经管理与预算办公室批准，OMB控制号0910-0149）
修订历史
1989年2月2 日《美国联邦公报》54卷5228页
1998年11月4 日《美国联邦公报》63卷59470页

211.134 Drug product inspection
药品检查

(a) Packaged and labeled products shall be examined during finishing operations to provide assurance that containers and packages in the lot have the correct label.
在贴标和包装的操作过程中应进行检查，以确保该批中产品使用了正确的标签和包材。

(b) A representative sample of units shall be collected at the completion of finishing operations and shall be visually examined for correct labeling.
在最后操作完成时，应收集代表性样品单元，并通过目检检查标签的正确性。

(c) Results of these examinations shall be recorded in the batch production or control records.
这些检查的结果应记录在批生产或控制记录中。

211.137 Expiration dating
有效期（1995年1月20日）

(a) To assure that a drug product meets applicable standards of identity, strength, quality, and purity at the time of use, it shall bear an expiration date determined by appropriate stability testing described in § 211.166.
为确保药品在使用时符合鉴别、规格、质量和纯度的相应标准，应按照Sec. 211.166 中规定的稳定性试验结果确定药品有效期。

(b) Expiration dates shall be related to any storage conditions stated on the labeling, as determined by stability studies described in § 211.166.
根据在 Sec. 211.166 中描述的稳定性研究确定，有效期应与标签标示的贮存条件有关。

(c) If the drug product is to be reconstituted at the time of dispensing, its labeling shall bear expiration

information for both the reconstituted and unreconstituted drug products.

如果药品在使用时需要重新分瓶使用，则标签上应具有开瓶有效期和产品有效期信息。

(d) Expiration dates shall appear on labeling in accordance with the requirements of § 201.17 of this Chapter.

根据本章 Sec. 201.17 的要求，有效期应标注在标签上。

§ 201.17 Drugs; location of expiration date.

When an expiration date of a drug is required, e.g., expiration dating of drug products required by § 211.137 of this chapter, it shall appear on the immediate container and also the outer package, if any, unless it is easily legible through such outer package. However, when single-dose containers are packed in individual cartons, the expiration date may properly appear on the individual carton instead of the immediate product container.）

§ 201.17药品有效期的位置

当某种药物具有有效期时，例如本章第211.137节要求的药物有效期，除非通过外包装容易辨认。它应出现在直接包装产品的容器和外包装上（如果有的话），但是，如果将单个剂量的产品包装在单独的纸盒中，则有效期可能显示在单独的纸盒上，而不是直接在使用的产品容器上。）

(e) Homeopathic drug products shall be exempt from the requirements of this Section.

顺势疗法的药品豁免于本节要求。

(f) Allergenic extracts that are labeled “No U.S. Standard of Potency” are exempt from the requirements of this Section.

标示“无美国效价标准”的过敏原提取物豁免于本节要求。

(g) New drug products for investigational use are exempt from the requirements of this Section, provided that they meet appropriate standards or specifications as demonstrated by stability studies during their use in clinical investigations. Where new drug products for investigational use are to be reconstituted at the time of dispensing, their labeling shall bear expiration information for the reconstituted drug product.

用于临床研究使用的新药产品不受本节要求的约束，前提是它们符合稳定性研究在临床调查期间所证明的适当标准或规格。新药在配药时需要重组的，其标签应当带有重组药品的有效期。

(h) Pending consideration of a proposed exemption, published in the Federal Register of September 29, 1978, the requirements in this Section shall not be enforced for human OTC drug products if their labeling does not bear dosage limitations and they are stable for at least 3 years as supported by appropriate stability data.

经考虑 1978 年 9 月 29 日《联邦公报》上发表的豁免提议，本章节的要求不强制应用于标签未标注剂量限制，且根据适当的稳定性数据证实可在至少三年期间保持稳定的人用 OTC 药品。

[43 FR 45077, Sept. 29, 1978, as amended at 46 FR 56412, Nov. 17, 1981; 60 FR 4091, Jan. 20, 1995]

修订历史

1978年9月29日《美国联邦公报》43卷45077页

1981年11月17日《美国联邦公报》46卷56412页

1995年1月20日《美国联邦公报》60卷4091页

Subpart H - Holding and Distribution

贮存和发运

211.142 Warehousing procedures

入库程序

Written procedures describing the warehousing of drug products shall be established and followed. They shall include:

应制订并遵循有关药品入库的书面程序。程序应包括：

(a) Quarantine of drug products before release by the quality control unit.

质检部门在放行前对药品进行检验。

(b) Storage of drug products under appropriate conditions of temperature, humidity, and light so that the identity, strength, quality, and purity of the drug products are not affected.

药品在适宜湿度、湿度和光线条件下的贮存，不影响药品的鉴别、规格、质量和纯度。

211.150 Distribution procedures

发运程序

Written procedures shall be established, and followed, describing the distribution of drug products. They shall include:

应制订并遵循有关药品发运的书面程序。该程序应包括：

(a) A procedure whereby the oldest approved stock of a drug product is distributed first. Deviation from this requirement is permitted if such deviation is temporary and appropriate.

首先发放最先经批准放行的药品。可以允许偏离此要求，但这种偏差应是零时或适当的。

(b) A system by which the distribution of each lot of drug product can be readily determined to facilitate its recall if necessary.

需要有一个能确定每批药品发运情况的系统，必要时便于召回。

Subpart I - Laboratory Controls

实验室管理

211.160 General requirements

一般要求（2008年9月8日）

(a) The establishment of any specifications, standards, sampling plans, test procedures, or other laboratory control mechanisms required by this Subpart, including any change in such specifications, standards, sampling plans, test procedures, or other laboratory control mechanisms, shall be drafted by the appropriate organizational unit and reviewed and approved by the quality control unit. The requirements in this Subpart shall be followed and shall be documented at the time of performance. Any deviation from the written specifications, standards, sampling plans, test procedures, or other laboratory control mechanisms shall be recorded and justified.

对本子部所要求制订的所有质量标准、标准、取样方案、检验规程或其它实验室控制机制，包括这些质量标准、标准、取样方案、检验规程或其它实验室控制机制的变更，应由合适的部门起草，并由质量管理部门审核和批准。应遵循本子部的要求并即时做好记录。所有偏离既定质量标准、标准、取样方案、检验程序或其它实验室控制机制的偏差，均应记录并作出合理解释。

(b) Laboratory controls shall include the establishment of scientifically sound and appropriate specifications, standards, sampling plans, and test procedures designed to assure that components, drug product containers, closures, in-process materials, labeling, and drug products conform to appropriate standards of identity, strength, quality, and purity. Laboratory controls shall include:

实验室控制应包括制订科学可靠和恰当的质量标准、标准、取样方案和检验规程，以保证原辅料、药品容器、密封件、中间产品、标签和药品符合适当的鉴别、规格、质量和纯度的标准。实验室控制应包括：

(1) Determination of conformity to applicable written specifications for the acceptance of each lot within each shipment of components, drug product containers, closures, and labeling used in the manufacture, processing, packing, or holding of drug products. The specifications shall include a description of the sampling and testing procedures used. Samples shall be representative and adequately identified. Such procedures shall also require appropriate retesting of any component, drug product container, or closure that is subject to deterioration.

确定每次运输到货的每一批用于药品生产、加工、包装或贮存的原辅料、药品容器、密封件和标签符合合适的书面质量标准。质量标准应包括对使用的取样及检验方法的描述。样品应具有代表性并有适当标识。此类规程还要求对易变质的原辅料、药品容器或密封件进行适当的复验。

(2) Determination of conformance to written specifications and a description of sampling and testing procedures for in-process materials. Such samples shall be representative and properly identified.

应有生产用物料的书面质量标准与取样描述及检验规程，并符合要求。此类样品应具有代表性并适当标识。

(3) Determination of conformance to written descriptions of sampling procedures and appropriate specifications for drug products. Such samples shall be representative and properly identified.

应有产品的书面质量标准与取样描述及检验规程，并符合要求。此类样品应具有代表性并适当标识。

(4) The calibration of instruments, apparatus, gauges, and recording devices at suitable intervals in accordance with an established written program containing specific directions, schedules, limits for accuracy and precision, and provisions for remedial action in the event accuracy and/or precision limits are not met. Instruments, apparatus, gauges, and recording devices not meeting established specifications shall not be used.

按照制订的包含有具体说明、时间计划、精确度和精密度限度，以及在精确度和/或精密度超出限度情况

的矫正措施预案的书面方案，定期对仪器、装置、计量器具和记录设备进行校准。不符合既定质量标准的仪器、装置、计量器具和记录设备不得予以使用

[43 FR 45077, Sept. 29, 1978, as amended at 73 FR 51932, Sept. 8, 2008]

修订历史

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2008年9月8 日《美国联邦公报》73卷51932页

211.165 Testing and release for distribution

检验与发运放行

(a) For each batch of drug product, there shall be appropriate laboratory determination of satisfactory conformance to final specifications for the drug product, including the identity and strength of each active ingredient, prior to release. Where sterility and/or pyrogen testing are conducted on specific batches of shortlived radiopharmaceuticals, such batches may be released prior to completion of sterility and/or pyrogen testing, provided such testing is completed as soon as possible.

每批药品放行前，应对其与药品最终质量标准（包括每一活性成份的鉴别和规格）的完全符合性进行适当的实验室判定。当对有效期短的放射性药物特定的批次进行无菌和/或热原检测时，只要这些检测能尽快完成，该批次可以在无菌和/或热原检测完成前放行。

(b) There shall be appropriate laboratory testing, as necessary, of each batch of drug product required to be free of objectionable microorganisms.

必要时，对要求无有害微生物污染的药品，每一批均应进行适当的实验室检验。

(c) Any sampling and testing plans shall be described in written procedures that shall include the method of sampling and the number of units per batch to be tested; such written procedure shall be followed.

所有取样及取样计划均应在操作规程中进行描述，应包括取样方法和每个供检批次的样品数量，并遵照执行该书面规程

(d) Acceptance criteria for the sampling and testing conducted by the quality control unit shall be adequate to assure that batches of drug products meet each appropriate specification and appropriate statistical quality control criteria as a condition for their approval and release. The statistical quality control criteria shall include appropriate acceptance levels and/or appropriate rejection levels.

质量控制部门使用的取样和检验的验收标准，应能充分保证各批药品符合适当的质量标准和适当的质量趋势（OOT），以此作为批准和放行的条件。统计质量控制标准应包括适当的接受水平和/或适当的拒收水平。

(e) The accuracy, sensitivity, specificity, and reproducibility of test methods employed by the firm shall be established and documented. Such validation and documentation may be accomplished in accordance with § 211.194(a)(2).

企业应建立并记录所采用的检验方法的精确度、灵敏度、特异性和重现性。按照 Sec. 211.194(a)(2)完成此类验证和记录

(f) Drug products failing to meet established standards or specifications and any other relevant quality control criteria shall be rejected. Reprocessing may be performed. Prior to acceptance and use, reprocessed material must meet appropriate standards, specifications, and any other relevant criteria.

不符合制订的标准或质量标准或其它相关质量控制标准的药品应予拒收。可采取返工。在接受和使用前，返工物料必须符合适当的标准、质量标准和任何其它相关的标准。

211.166 Stability testing

稳定性试验（1981年11月17日）

(a) There shall be a written testing program designed to assess the stability characteristics of drug products. The results of such stability testing shall be used in determining appropriate storage conditions and expiration dates. The written program shall be followed and shall include:

应制订评估药品稳定性特征的书面试验方案。稳定性试验的结果应用于判断适当的贮存条件和有效期。该书面方案应被遵循，并包括：

(1) Sample size and test intervals based on statistical criteria for each attribute examined to assure valid estimates of stability;

根据每个检测的属性的统计学标准（综合检测样品需求量，各质量属性的检测周期统计）制订取样量和测试周期，以保证对稳定性的有效评估。

(2) Storage conditions for samples retained for testing;

试验留样的贮存条件。

(3) Reliable, meaningful, and specific test methods;
可靠的、有意义和明确的试验方法。
(4) Testing of the drug product in the same container-closure system as that in which the drug product is marketed;
试验用的药品储存在与上市药品相同的容器-密封系统内。
(5) Testing of drug products for reconstitution at the time of dispensing (as directed in the labeling) as well as after they are reconstituted.
应对药品使用时采用的原包装进行测试（按标签指示）和分装后进行测试；

(b) An adequate number of batches of each drug product shall be tested to determine an appropriate expiration date and a record of such data shall be maintained. Accelerated studies, combined with basic stability information on the components, drug products, and container-closure system, may be used to support tentative expiration dates provided full shelf life studies are not available and are being conducted. Where data from accelerated studies are used to project a tentative expiration date that is beyond a date supported by actual shelf life studies, there must be stability studies conducted, including drug product testing at appropriate intervals, until the tentative expiration date is verified or the appropriate expiration date determined.
每个药品有足够数量的批次用于确定适当的有效期，这些数据记录应予保存。如果不能提供整个货架期的数据，且研究在进行中，则可使用结合原辅料、药品和容器—封闭系统稳定性信息的加速试验来支持暂定的有效期。如果加速试验的数据用于预计超出实际货架期研究支持的日期的暂定有效期时，必须进行稳定性研究，包括适当间隔的测试，直至暂定的有效期被证实或确定出适宜的有效期。

(c) For homeopathic drug products, the requirements of this Section are as follows:
对于顺势疗法的药品，本节作如下要求。
(1) There shall be a written assessment of stability based at least on testing or examination of the drug product for compatibility of the ingredients, and based on marketing experience with the drug product to indicate that there is no degradation of the product for the normal or expected period of use.
应至少根据药物成分的测试或检验对成分的稳定性进行书面稳定性评估，并根据与药品的营销经验，表明该产品在正常或预期使用期间不会变质。
(2) Evaluation of stability shall be based on the same container-closure system in which the drug product is being marketed.
稳定性评估，应基于与药品上市使用的相同容器—封闭系统相同。

(d) Allergenic extracts that are labeled “No U.S. Standard of Potency” are exempt from the requirements of this Section.
标示“无美国效价标准”的过敏原提取物豁免于本节要求。

[43 FR 45077, Sept. 29, 1978, as amended at 46 FR 56412, Nov. 17, 1981]
修订历史
1978年9月29日《美国联邦公报》43卷45077页
1981年11月17 日《美国联邦公报》46卷56412页

211.167 Special testing requirements
特殊检验要求

(a) For each batch of drug product purporting to be sterile and/or pyrogen-free, there shall be appropriate laboratory testing to determine conformance to such requirements. The test procedures shall be in writing and shall be followed.
对每批无菌和/或无热原的药品，应进行适当的实验室检验以确定其与要求相符。应制订并遵循关于检验规程的书面规程。

(b) For each batch of ophthalmic ointment, there shall be appropriate testing to determine conformance to specifications regarding the presence of foreign Particles and harsh or abrasive substances. The test procedures shall be in writing and shall be followed.
对每批眼膏均应进行适当的检验，以确定其颗粒异物和粗糙物或磨损产物符合相关质量标准。应制订并遵循关于检验规程的书面规程。

(c) For each batch of controlled-release dosage form, there shall be appropriate laboratory testing to determine conformance to the specifications for the rate of release of each active ingredient. The test procedures shall be in writing and shall be followed.
对每批控释剂应进行适当的实验室检验，以确定与每一活性成份释放速率符合质量标准。应制订并遵循关于检

验规程的书面规程。

211.170 Reserve samples

留样（1995年1月20日）

(a) An appropriately identified reserve sample that is representative of each lot in each shipment of each active ingredient shall be retained. The reserve sample consists of at least twice the quantity necessary for all tests required to determine whether the active ingredient meets its established specifications, except for sterility and pyrogen testing. The retention time is as follows:

每次运输的每批货物的每一活性成份的留样都应进行适当标识及保存。留样应有进行活性成份是否符合既定质量标准全部检查的必需量的至少两倍，无菌和热原检验的除外。保留时间如下。（API）

(1) For an active ingredient in a drug product other than those described in Paragraph s (a) (2) and (3) of this Section, the reserve sample shall be retained for 1 year after the expiration date of the last lot of the drug product containing the active ingredient.

除本节(a) (2) 和(3)描述的之外，对于药品中的活性成份，留样应保存至含活性成份药品的最后一批有效期后 1 年。

(2) For an active ingredient in a radioactive drug product, except for nonradioactive reagent kits, the reserve sample shall be retained for:

对于除非放射活性的试剂盒以外的放射性药品中的活性成份，留样应保存至：

(i) Three months after the expiration date of the last lot of the drug product containing the active ingredient if the expiration dating period of the drug product is 30 days or less; or

如果药品的有效期为 30 天或以内，则应为最后一批含活性成份药品的有效期后 3 个月；或

(ii) Six months after the expiration date of the last lot of the drug product containing the active ingredient if the expiration dating period of the drug product is more than 30 days.

如果药品的有效期为 30 天以上，则应为最后一批含活性成份药品的有效期后 6 个月。

(3) For an active ingredient in an OTC drug product that is exempt from bearing an expiration date under § 211.137, the reserve sample shall be retained for 3 years after distribution of the last lot of the drug product containing the active ingredient.

根据 Sec. 211.137 免于标注有效期的 OTC 药物中的活性成份，留样应保留至最后一批含活性成份药品发运后的 3 年。

(b) An appropriately identified reserve sample that is representative of each lot or batch of drug product shall be retained and stored under conditions consistent with product labeling. The reserve sample shall be stored in the same immediate container-closure system in which the drug product is marketed or in one that has essentially the same characteristics. The reserve sample consists of at least twice the quantity necessary to perform all the required tests, except those for sterility and pyrogens. Except for those for drug products described in Paragraph (b)(2) of this Section, reserve samples from representative sample lots or batches selected by acceptable statistical procedures shall be examined visually at least once a year for evidence of deterioration unless visual examination would affect the integrity of the reserve sample. Any evidence of reserve sample deterioration shall be investigated in accordance with § 211.192. The results of the examination shall be recorded and maintained with other stability data on the drug product. Reserve samples of compressed medical gases need not be retained. The retention time is as follows:

每批或整批药品的有适当标识的代表性留样应被保留且在与标签一致的贮存条件下保存。留样应该在与药品市售包装相同或具有相同特性的内包装材料中贮存。留样（用于无菌和热原的除外）至少应包含进行全部检查所必须量的二倍。除本节(b)(2)中所述的药品外，根据可接受统计程序所选择的批或整批的代表性样品的留样，每年应对变质迹象进行一次目检检查，除非目检会影响留样的完整性。根据 Sec.211.192，对留样的任何变质迹象进行调查。检查结果应作记录并与其它药品稳定性数据一起保存。医用压缩气体的留样无需保留。保留时间如下：

(1) For a drug product other than those described in Paragraph s (b) (2) and (3) of this Section, the reserve sample shall be retained for 1 year after the expiration date of the drug product.

除本节(b) (2)和(3)段中所述的药品外，留样应保存至药品有效期后一年

(2) For a radioactive drug product, except for nonradioactive reagent kits, the reserve sample shall be retained for:

除非放射性试剂盒之外的放射性药品，留样应保存至：

(i) Three months after the expiration date of the drug product if the expiration dating period of the drug product is 30 days or less; or

如果药品的有效期为 30 天或以内，则应为药品的有效期后 3 个月；或

(ii) Six months after the expiration date of the drug product if the expiration dating period of the drug product is more than 30 days.
如果药品的有效期为 30 天以上，则应为药品的有效期后 6 个月

(3) For an OTC drug product that is exempt for bearing an expiration date under § 211.137, the reserve sample must be retained for 3 years after the lot or batch of drug product is distributed.
根据 Sec. 211.137 免于标注有效期的 OTC 药物，留样必须保留至该批或整批药品发运后的 3 年。

[48 FR 13025, Mar. 29, 1983, as amended at 60 FR 4091, Jan. 20, 1995]
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1983年3月29 日《美国联邦公报》48卷13025页
1995年1月20 日《美国联邦公报》60卷4091页

211.173 Laboratory animals
实验动物

Animals used in testing components, in-process materials, or drug products for compliance with established specifications shall be maintained and controlled in a manner that assures their suitability for their intended use. They shall be identified, and adequate records shall be maintained showing the history of their use.

用于检测原辅料、中间产品或药品与既定质量标准符合性的动物，应以保证它们预期用途适用性的方式进行饲养和控制。对它们应进行鉴别，并保存详细的使用历史记录。

211.176 Penicillin contamination
青霉素污染（2016年7月29日）

If a reasonable possibility exists that a non-penicillin drug product has been exposed to cross-contamination with penicillin, the non-penicillin drug product shall be tested for the presence of penicillin. Such drug product shall not be marketed if detectable levels are found when tested according to procedures specified in 'Procedures for Detecting and Measuring Penicillin Contamination in Drugs,' which is incorporated by reference. Copies are available from the Division of Research and Testing (HFD-470), Center for Drug Evaluation and Research, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, or available for inspection 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.

如果存在非青霉素药品与青霉素接触并致交叉污染的合理的可能性，则非青霉素药品应进行青霉素是否存在的检查。如果根据《药物中青霉素污染的检定和计量规程》（附参考）说明的程序进行检验时发现已达到可检出水平，则该药不得进行销售。规程副本可以从食品药品管理局药物评价研究中心的药物研究检验所（HFD-470）索取或者联邦公报办公室（5001 Campus Dr., College Park, MD 20740）处查阅，或者国家档案和记录管理局（National Archives and Records Administration，NARA）。欲了解 NARA 关于此材料的可获取性信息，请拨打 202-741-6030 或访问：
http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

[43 FR 45077, Sept. 29, 1978, as amended at 47 FR 9396, Mar. 5, 1982; 50 FR 8996, Mar. 6, 1985; 55 FR 11577, Mar. 29, 1990; 66 FR 56035, Nov. 6, 2001; 69 FR 18803, Apr. 9, 2004; 81 FR 49897, July 29, 2016]
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Subpart J - Records and Reports
记录和报告

211.180 General requirements

一般要求（1995年1月20日）

(a) Any production, control, or distribution record that is required to be maintained in compliance with this Part and is specifically associated with a batch of a drug product shall be retained for at least 1 year after the expiration date of the batch or, in the case of certain OTC drug products lacking expiration dating because they meet the criteria for exemption under § 211.137, 3 years after distribution of the batch.

按照本部分要求保存的，以及尤其是与一批药品相关的所有的生产、控制和发运的记录，至少应保存至该批有效期后 1 年，或者，对于达到 Sec. 211.137 的豁免标准而无有效期的某些 OTC 药品，应保存至该批发运后 3 年。

(b) Records shall be maintained for all components, drug product containers, closures, and labeling for at least 1 year after the expiration date or, in the case of certain OTC drug products lacking expiration dating because they meet the criteria for exemption under § 211.137, 3 years after distribution of the last lot of drug product incorporating the component or using the container, closure, or labeling.

所有原辅料、药品容器、密封件和标签的记录至少应保存有效期后 1 年，或者，对于达到 Sec. 211.137的豁免标准而无有效期的某些 OTC 药品，保留至采用原辅料或药品包装容器、密封件或标签的最后一批药品发运后 3 年。

(c) All records required under this Part, or copies of such records, shall be readily available for authorized inspection during the retention period at the establishment where the activities described in such records occurred. These records or copies thereof shall be subject to photocopying or other means of reproduction as Part of such inspection. Records that can be immediately retrieved from another location by computer or other electronic means shall be considered as meeting the requirements of this Paragraph .

本章节要求的所有记录，或此类记录的副本，在保留期间，应在发生此类记录描述的活动的企业，可以随时接受授权的检查。作为此类检查的一部分，这些记录或其副本可进行影印或其它方式的复制在其他厂址。通过计算机或其它电子方式可即时检索的记录，应被认为是符合本段要求的。

(d) Records required under this Part may be retained either as original records or as true copies such as photocopies, microfilm, microfiche, or other accurate reproductions of the original records. Where reduction techniques, such as microfilming, are used, suitable reader and photocopying equipment shall be readily available.

本部分所需的记录可以原始记录或真实副本（诸如影印、微型胶卷、单片缩影胶片或其它原始记录的精确复制品）的形式进行保存。使用缩影技术（如微型胶卷）的地方应随时可以提供合适的阅读器和影印设备。

(e) Written records required by this Part shall be maintained so that data therein can be used for evaluating, at least annually, the quality standards of each drug product to determine the need for changes in drug product specifications or manufacturing or control procedures. Written procedures shall be established and followed for such evaluations and shall include provisions for:

本部分所需的书面记录应予保存，以便使其中的数据可以用于至少每年一次的每一药品质量标准的评估，以确定药品质量标准、生产或控制规程的变更需求。应制订并遵循此类评估的书面规程，并应包括规定。

(1) A review of a representative number of batches, whether approved or rejected, and, where applicable, records associated with the batch.

对一定代表性数量包括接受或拒收的产品批次及相关的记录的回顾。

(2) A review of complaints, recalls, returned or salvaged drug products, and investigations conducted under § 211.192 for each drug product.

对每一药品的投诉、召回、退货或回收的审核，及根据 Sec. 211.192 展开的调查。

(f) Procedures shall be established to assure that the responsible officials of the firm, if they are not personally involved in or immediately aware of such actions, are notified in writing of any investigations conducted under §§ 211.198, 211.204, or 211.208 of these regulations, any recalls, reports of inspectional observations issued by the Food and Drug Administration, or any regulatory actions relating to good manufacturing practices brought by the Food and Drug Administration.

应制订规程以保证企业负责人，在他们没有亲临或即时获知这类行为时，应被书面告知关于根据法规§Sec. 211.198, 211.204, 或 211.208 部分进行的调查、任何召回、FDA 发的检查观察项报告、或 FDA 关于CGMP 的所有监管行动。

[43 FR 45077, Sept. 29, 1978, as amended at 60 FR 4091, Jan. 20, 1995]

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1995年1月20 日《美国联邦公报》60卷8996页

211.182 Equipment cleaning and use log

设备的清洁和使用记录（2008年9月8日）

A written record of major equipment cleaning, maintenance (except routine maintenance such as lubrication and adjustments), and use shall be included in individual equipment logs that show the date, time, product, and lot number of each batch processed. If equipment is dedicated to manufacture of one product, then individual equipment logs are not required, provided that lots or batches of such product follow in numerical order and are manufactured in numerical sequence. In cases where dedicated equipment is employed, the records of cleaning, maintenance, and use shall be Part of the batch record. The persons performing and double-checking the cleaning and maintenance (or, if the cleaning and maintenance is performed using automated equipment under § 211.68, just the person verifying the cleaning and maintenance done by the automated equipment) shall date and sign or initial the log indicating that the work was performed. Entries in the log shall be in chronological order.

关于主要设备的清洁、维护（日常维护如润滑和调试除外）和使用的书面记录应包括在单独的显示日期、时间、产品和加工的每批批号的设备日志中。如果设备专用于一个产品的生产，而且此产品的批次按数字顺序排列并按数字顺序生产，则不需要单独的设备日志。在使用专用设备时，清洁、维护和使用的记录应作为批记录的一部分。操作和复核的清洁、维护的人员（如果采用根据 211.68 所述自动化设备来完成清洁和维护工作，那么只需核实自动化设备完成清洁与维护工作的人员）应在日志上注明日期并签名或用首字母标记，表明工作已完成。日志应按时间顺序填写。

[73 FR 51933, Sept. 8, 2008]
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211.184 Component, drug product container, closure, and labeling records.

原辅料、药品容器、密封件及标签记录

These records shall include the following:

这些记录应包括下面内容:

(a) The identity and quantity of each shipment of each lot of components, drug product containers, closures, and labeling; the name of the supplier; the supplier's lot number(s) if known; the receiving code as specified in § 211.80; and the date of receipt. The name and location of the prime manufacturer, if different from the supplier, shall be listed if known.

每批原辅料、药品容器、密封件和标签每次到货的鉴别和数量；供应商名称；供应商的批号（已知的话）；Sec. 211.80 规定的接收代码；和接收日期。如果主要生产商非供应商，应列出主要生产商名称和地址（已知的话）

(b) The results of any test or examination performed (including those performed as required by § 211.82(a), § 211.84(d), or § 211.122(a)) and the conclusions derived therefrom.

任何所做检验或检查的结果（包括根据 Sec. 211.82(a), Sec. 211.84(d), or Sec. 211.122(a)要求做的），以及由其得出的结论。

(c) An individual inventory record of each component, drug product container, and closure and, for each component, a reconciliation of the use of each lot of such component. The inventory record shall contain sufficient information to allow determination of any batch or lot of drug product associated with the use of each component, drug product container, and closure.

每一原辅料、药品容器和密封件的库存记录，针对每一原辅料，每批该原辅料的使用物料平衡。台账记录应包括足够的信息以确定每一原辅料、药品容器和密封件投入使用的药品批次

(d) Documentation of the examination and review of labels and labeling for conformity with established specifications in accord with §§ 211.122(c) and 211.130(c).

根据Sec. 211.122(c) 和Sec. 211.130(c)制订的质量标准，对标签进行相符性检查和审核的文件。

(e) The disposition of rejected components, drug product containers, closure, and labeling.

不合格原辅料、药品容器、密封件、标签的处理记录

211.186 Master production and control records

生产和控制主记录

(a) To assure uniformity from batch to batch, master production and control records for each drug product, including each batch size thereof, shall be prepared, dated, and signed (full signature, handwritten) by one person and independently checked, dated, and signed by a second person. The preparation of master

production and control records shall be described in a written procedure and such written procedure shall be followed.

为保证批次间的均一性，每一药品（包括所有的批量在内）的主生产和控制记录应由一人准备、注明日期和署名（全名，手写），并由第二人独立核对、注明日期和署名。应制订并遵循关于生产与控制主记录的准备操作的书面规程。

(b) Master production and control records shall include:

生产与控制主记录应包括：

(1) The name and strength of the product and a description of the dosage form;

产品的名称和规格及剂型描述。

(2) The name and weight or measure of each active ingredient per dosage unit or per unit of weight or measure of the drug product, and a statement of the total weight or measure of any dosage unit;

在药品的每个单位剂量或单位重量或体积中，每种活性成分的名称和重量或度量，及所有单位剂量的总重量或度量的说明。

(3) A complete list of components designated by names or codes sufficiently specific to indicate any special quality characteristic;

由名称或者代码指定的、足以表明特殊质量特征的完整的原辅料清单：

(4) An accurate statement of the weight or measure of each component, using the same weight system (metric, avoirdupois, or apothecary) for each component. Reasonable variations may be permitted, however, in the amount of components necessary for the preparation in the dosage form, provided they are justified in the master production and control records;

每一原辅料重量或体积的准确说明，对每一原辅料使用相同的重量系统（公制、常衡制或药衡制）。不过，如果在生产与控制主记录有合理性说明，在剂型制备必须的原辅料数量中允许有合理的偏差。

(5) A statement concerning any calculated excess of component;

有关原辅料的计算过量（超量投料）的说明；

(6) A statement of theoretical weight or measure at appropriate phases of processing;

在适当的加工阶段的理论重量或度量的说明；

(7) A statement of theoretical yield, including the maximum and minimum percentages of theoretical yield beyond which investigation according to § 211.192 is required;

理论产量的说明，包括根据 211.92 要求对超出理论产量的最大和最小百分率的调查。

(8) A description of the drug product containers, closures, and packaging materials, including a specimen or copy of each label and all other labeling signed and dated by the person or persons responsible for approval of such labeling;

药品容器、密封件和包装材料的描述，包括带有标签批准负责人签名并注日期的标签和所有其它类型标签的样本或副本。

(9) Complete manufacturing and control instructions, sampling and testing procedures, specifications, special notations, and precautions to be followed.

应遵循的完整的生产和控制指令、取样和检验规程、质量标准、特别注释及注意事项。

211.188 Batch production and control records

批生产与控制记录（2008年9月8日）

Batch production and control records shall be prepared for each batch of drug product produced and shall include complete information relating to the production and control of each batch. These records shall include:

应为生产的每批药品准备批生产与控制的记录，并包括与每批生产和控制有关的完整信息。这些记录应包括：

(a) An accurate reproduction of the appropriate master production or control record, checked for accuracy, dated, and signed;

适当主生产或控制记录的精确附件，已检查准确性、注明日期并签名。

(b) Documentation that each significant step in the manufacture, processing, packing, or holding of the batch was accomplished, including:

批的生产、加工、包装或贮存中各重要步骤的记录，包括：

(1) Dates;

日期

(2) Identity of individual major equipment and lines used;

使用的单个主要设备和生产线的身份。

(3) Specific identification of each batch of component or in-process material used;

使用的每批原辅料或中间产品的具体信息

(4) Weights and measures of components used in the course of processing;

加工过程中使用的原辅料的重量和度量；

(5) In-process and laboratory control results;
工艺和实验室控制结果。

(6) Inspection of the packaging and labeling area before and after use;
包装和贴签区域使用前后的检查。

(7) A statement of the actual yield and a statement of the percentage of theoretical yield at appropriate phases of processing;
适当加工阶段的实际产量的说明和理论收率的说明

(8) Complete labeling control records, including specimens or copies of all labeling used;
完整的标签控制记录，包括所有使用标签的样本或副本。

(9) Description of drug product containers and closures;
药品容器和密封件的说明。

(10) Any sampling performed;
所有取样；

(11) Identification of the persons performing and directly supervising or checking each significant step in the operation, or if a significant step in the operation is performed by automated equipment under § 211.68, the identification of the person checking the significant step performed by the automated equipment.
各关键工序操作人员、直接管理人员或复核关键步骤人员的身份；或者，若采用 211.68 所述的自动化设备进行关键步骤操作，则应有检查自动化设备对关键工序完成情况的复核人员身份；

(12) Any investigation made according to § 211.192.
根据 Sec. 211.192 所做的任何调查

(13) Results of examinations made in accordance with § 211.134.
根据 Sec. 211.134 所做检查的结果。

[43 FR 45077, Sept. 29, 1978, as amended at 73 FR 51933, Sept. 8, 2008]
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211.192 Production record review
生产记录审核

All drug product production and control records, including those for packaging and labeling, shall be reviewed and approved by the quality control unit to determine compliance with all established, approved written procedures before a batch is released or distributed. Any unexplained discrepancy (including a percentage of theoretical yield exceeding the maximum or minimum percentages established in master production and control records) or the failure of a batch or any of its components to meet any of its specifications shall be thoroughly investigated, whether or not the batch has already been distributed. The investigation shall extend to other batches of the same drug product and other drug products that may have been associated with the specific failure or discrepancy. A written record of the investigation shall be made and shall include the conclusions and followup.

在批放行或发运之前，所有药品生产与控制记录（包括包装与贴签）都应由质量管理部门进行审核和批准，以确定与所有既定的批准的书面规程的符合情况。不管该批是否已经发运，所有未解释的差异（包括超出生产与控制主记录中设定的最大或最小限度的理论收率）或一批或其任何原辅料不符合质量标准的情况，都应进行彻底调查。调查应扩大至相同药品的其它批次和与差异或不合格情况相关的其它药品。调查应作出书面记录并应包括结论和追踪情况。

211.194 Laboratory records
实验室记录（2005年11月8日）

(a) Laboratory records shall include complete data derived from all tests necessary to assure compliance with established specifications and standards, including examinations and assays, as follows:

实验室记录应包括所有用于确认与既定质量标准或标准相符的必检项目所产生的完整数据，包括检查和化验，内容如下：

(1) A description of the sample received for testing with identification of source (that is, location from where sample was obtained), quantity, lot number or other distinctive code, date sample was taken, and date sample was received for testing.

收到的检验用样品的描述：来源鉴别（即，获取样品的地点）、数量、批号或其它区别代码、取样日期和检验用样品的收到日期。

(2) A statement of each method used in the testing of the sample. The statement shall indicate the location of data that establish that the methods used in the testing of the sample meet proper standards of accuracy and reliability as applied to the product tested. (If the method employed is in the current revision of the United States Pharmacopeia, National Formulary, AOAC INTERNATIONAL, Book of Methods, 1 or in other recognized standard references, or is detailed in an approved new drug application and the referenced method is not modified, a statement indicating the method and reference will suffice). The suitability of all testing methods used shall be verified under actual conditions of use.

检验样品使用的每种方法的说明。该说明应包含明确了在产品检验当中，样品的检验方法符合相应的准确性和可靠性标准的数据的位置。（如果使用的方法为现行版本的《美国药典》、《国家处方集》、官方分析化学家协会《方法书》[1]，或其它公认的标准文献，或在已批准新药申请中有详述且参考方法未经修改，声明方法和参考资料即可）。应在实际使用条件下对所有使用的检测方法适用性进行核实。

[1] Copies may be obtained from: AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877.

[1] 副本可从以下地址获得：官方分析化学家协会，地址：北弗雷德里克大街481号，马里兰州盖瑟斯堡500室，20877。

(3) A statement of the weight or measure of sample used for each test, where appropriate.

适当时，每项检验使用的样品的重量或度量的适当说明。

(4) A complete record of all data secured in the course of each test, including all graphs, charts, and spectra from laboratory instrumentation, properly identified to show the specific component, drug product container, closure, in-process material, or drug product, and lot tested.

每项检验过程中取得的所有数据的完整记录，包括实验室仪器测定的原辅料，药品容器，密封件，中间产品或药品及批次的图形、表格、光谱。

(5) A record of all calculations performed in connection with the test, including units of measure, conversion factors, and equivalency factors.

与检验相关的所有计算记录，包括度量单位、换算因子和等价因子。

(6) A statement of the results of tests and how the results compare with established standards of identity, strength, quality, and purity for the component, drug product container, closure, in-process material, or drug product tested.

检验结果的说明，以及结果与检验的原辅料、药品容器、密封件、中间产品或药品既定的鉴别、规格、质量和纯度的标准进行比较的过程。

(7) The initials or signature of the person who performs each test and the date(s) the tests were performed.

每项检验的操作人员的首字母或签名及检验操作日期。

(8) The initials or signature of a second person showing that the original records have been reviewed for accuracy, completeness, and compliance with established standards.

复核人员的首字母或签名，表明已对原始记录的准确性、完整性进行了审核并符合既定标准。

(b) Complete records shall be maintained of any modification of an established method employed in testing. Such records shall include the reason for the modification and data to verify that the modification produced results that are at least as accurate and reliable for the material being tested as the established method.

采用的既定检验方法的任何变更的完整记录都应保存。此类记录应包括修改原因和证明该变更产生的结果至少和既定方法同样准确和可靠的数据。

(c) Complete records shall be maintained of any testing and standardization of laboratory reference standards, reagents, and standard solutions.

应当保存所有实验室对照品、试剂和标准溶液的试验和标定的完整记录。

(d) Complete records shall be maintained of the periodic calibration of laboratory instruments, apparatus, gauges, and recording devices required by § 211.160(b)(4).

根据 Sec. 211.160(b)(4)的要求，保存对实验室仪器、装置、计量器具和记录设备定期校准的完整记录。

(e) Complete records shall be maintained of all stability testing performed in accordance with § 211.166.

应根据 Sec. 211.166 要求，保存所进行的稳定性试验的完整记录。

[43 FR 45077, Sept. 29, 1978, as amended at 55 FR 11577, Mar. 29, 1990; 65 FR 18889, Apr. 10, 2000; 70 FR 40880, July 15, 2005; 70 FR 67651, Nov. 8, 2005]

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211.196 Distribution records
发运记录（1984年3月16日）

Distribution records shall contain the name and strength of the product and description of the dosage form, name and address of the consignee, date and quantity shipped, and lot or control number of the drug product. For compressed medical gas products, distribution records are not required to contain lot or control numbers.

发运记录应包括产品的名称和规格，剂型描述、收货人的名称和地址、运输日期和数量以及药品的批号或控制号。对于医用压缩气体产品，发运记录不需要包括批号或控制号。

(Approved by the Office of Management and Budget under control number 0910-0139)
(管理和预算局批准编号0910-0139)

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211.198 Complaint files
投诉档案（2003年3月31 日）

(a) Written procedures describing the handling of all written and oral complaints regarding a drug product shall be established and followed. Such procedures shall include provisions for review by the quality control unit, of any complaint involving the possible failure of a drug product to meet any of its specifications and, for such drug products, a determination as to the need for an investigation in accordance with § 211.192. Such procedures shall include provisions for review to determine whether the complaint represents a serious and unexpected adverse drug experience which is required to be reported to the Food and Drug Administration in accordance with §§ 310.305 and 514.80 of this Chapter.

应制订和遵循药品相关的所有书面和口头投诉的书面规程。此类规程应包括由质量管理部门对所有涉及药品不符合任何质量标准的投诉进行审核的条款，根据 Sec. 211.192 要求决定是否需要对此类产品进行调查。此类规程应包括，根据本章 Sec. 310.305① 和 514.80② 进行的审核条款，以确定是否该投诉内容属于需要向 FDA 报告的严重的突发的药品不良事件。

①310.305 Records and reports concerning adverse drug experiences on marketed prescription drugs for human use without approved new drug applications.
①310.305 关于未经批准的新药申请而上市的人用处方药不良反应的记录和报告（仅标题，详细内容请查看原文）

②514.80 Records and reports concerning experience with approved new animal drugs.
②514.80关于已批准的动物新药物使用经验的记录和报告。（仅标题，详细内容请查看原文）

(b) A written record of each complaint shall be maintained in a file designated for drug product complaints. The file regarding such drug product complaints shall be maintained at the establishment where the drug product involved was manufactured, processed, or packed, or such file may be maintained at another facility if the written records in such files are readily available for inspection at that other facility. Written records involving a drug product shall be maintained until at least 1 year after the expiration date of the drug product, or 1 year after the date that the complaint was received, whichever is longer. In the case of certain OTC drug products lacking expiration dating because they meet the criteria for exemption under § 211.137, such written records shall be maintained for 3 years after distribution of the drug product.

药品投诉专用档案应保存每一投诉的书面记录。该药品投诉档案应保存在药品生产、加工或包装的企业内，或者，如果另一机构可随时接受文件书面记录的检查，则此档案可保存在该机构内。包含药品的书面记录应保存至药品有效期至少1 年后，或者收到投诉的日期后的 1 年，取其中较长的时间。对于符合 Sec. 211.137 豁免标准而无有效期的特定的 OTC 药品，此类书面记录应保存至药品发运后 3 年。

(1) The written record shall include the following information, where known: the name and strength of the

drug product, lot number, name of complainant, nature of complaint, and reply to complainant.

书面记录应包括以下已知的信息：药品的名称和规格、批号、投诉人姓名、投诉的性质及对投诉人的回复。

(2) Where an investigation under § 211.192 is conducted, the written record shall include the findings of the investigation and followup. The record or copy of the record of the investigation shall be maintained at the establishment where the investigation occurred in accordance with § 211.180(c).

如果根据 Sec. 211.192 展开了调查，书面记录应包括调查的发现和追踪情况。根据 Sec. 211.180(c)，调查记录或记录副本应保存在展开调查的企业内。

(3) Where an investigation under § 211.192 is not conducted, the written record shall include the reason that an investigation was found not to be necessary and the name of the responsible person making such a determination.

如果未根据 Sec. 211.192 展开调查，书面记录应包括发现不需要进行调查的原因，以及作此决定的负责人姓名。

[43 FR 45077, Sept. 29, 1978, as amended at 51 FR 24479, July 3, 1986; 68 FR 15364, Mar. 31, 2003]
[43 FR 45077， 1978年9月29日， 修订于 51 FR 24479， 1986年7月3 日; 68 FR 15364， 2003年3月31 日]
修订历史:

1978年9月29 日《美国联邦公报》43卷45077页
1986年7月3 日《美国联邦公报》51卷24479页
2003年3月31 日《美国联邦公报》68卷15364页

Subpart K - Returned and Salvaged Drug Products
药品退货与回收

211.204 Returned drug products
退货的药品

Returned drug products shall be identified as such and held. If the conditions under which returned drug products have been held, stored, or shipped before or during their return, or if the condition of the drug product, its container, carton, or labeling, as a result of storage or shipping, casts doubt on the safety, identity, strength, quality or purity of the drug product, the returned drug product shall be destroyed unless examination, testing, or other investigations prove the drug product meets appropriate standards of safety, identity, strength, quality, or purity. A drug product may be reprocessed provided the subsequent drug product meets appropriate standards, specifications, and characteristics. Records of returned drug products shall be maintained and shall include the name and label potency of the drug product dosage form, lot number (or control number or batch number), reason for the return, quantity returned, date of disposition, and ultimate disposition of the returned drug product. If the reason for a drug product being returned implicates associated batches, an appropriate investigation shall be conducted in accordance with the requirements of § 211.192. Procedures for the holding, testing, and reprocessing of returned drug products shall be in writing and shall be followed.

退货的药品应被标识后贮存。如果在退货药品退回之前或期间的 贮存或运输的条件，或因药品、其容器、纸箱或标签在贮存或运输中的状况，使药品在安全性、鉴别、规格、质量或纯度上出现疑问，则退货的药品应予销毁，除非检查、检验或其它调查证明药品符合适当的安全性、鉴别、规格、质量或纯度标准。如果随后的药品符合适当的标准、质量标准和性状，药品可以进行返工。退货药品的记录应予以保存并包括名称、药品剂型标示效价、批号（或控制号或整批号）、退货原因、退货数量、处理日期及退货药品的最终处理方法。如果药品退回的原因涉及相关批次，应根据 Sec. 211.192 要求展开适当的调查。应制订和遵循关于退货药品的贮存、检验、返工的书面规程。

211.208 Drug product salvaging
药品的回收

Drug products that have been subjected to improper storage conditions including extremes in temperature, humidity, smoke, fumes, pressure, age, or radiation due to natural disasters, fires, accidents, or equipment failures shall not be salvaged and returned to the marketplace. Whenever there is a question whether drug products have been subjected to such conditions, salvaging operations may be conducted only if there is

处于不当贮存条件，包括自然灾害、火灾、事故或设备故障造成的极端的温度、湿度、烟尘、烟雾、压力、老

化或辐射的药品不得予以回收并重新推向市场。对药品是否遭受此类条件存在疑问时，回收操作仅在以下情况 中可进行:

(a) evidence from laboratory tests and assays (including animal feeding studies where applicable) that the drug products meet all applicable standards of identity, strength, quality, and purity and

实验室检验和化验（包括适当的动物饲养）证明药品符合适用的鉴别、规格、质量和纯度标准，以及

(b) evidence from inspection of the premises that the drug products and their associated packaging were not

subjected to improper storage conditions as a result of the disaster or accident. Organoleptic examinations shall be acceptable only as supplemental evidence that the drug products meet appropriate standards of identity, strength, quality, and purity. Records including name, lot number, and disposition shall be maintained for drug products subject to this Section.

对厂房设施检查表明，药品及其相关包装并没有遭受灾害或事故所造成的不当贮存条件。感官检查仅可作为表 明药品符合适当的鉴别、规格、质量和纯度标准的补充性证据被接受。应保存本节涉及药品的记录，包括品名、批号和处理方法。