(10)所有取样；

(11) 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确认；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的身份确认；

(12) 根据Sec. 211.192所做的任何调查。

(13) 根据Sec. 211.134所做检查的结果。

Sec. 211.192 生产记录审核。

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。

Sec. 211.194 实验室记录。

(a) 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) 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) 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] 副本可自官方化学家协会（481 North Frederick Ave., suite 500, Gaithersburg, MD 20877）获得。

(3) 适当时，每项检验使用的样品的重量或度量的适当声明。

(4) 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) 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)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) 每项检验的操作人员的首字母或签名及检验操作日期。

(8) 第二人的首字母或签名，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) 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) 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) 根据Sec. 211.160(b)(4)的要求，保存对实验室仪器、仪表、计量器具和记录装置定期校准的完整记录。

(e) 应根据Sec. 211.166要求，保存所进行的稳定性试验的完整记录。

Sec. 211.196 发运记录

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。

Sec. 211.198 投诉档案

(a) 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. 310.305和514.80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。

(b) 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后1年，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) 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) 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) 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。

K子部- 药品退货与回收

Sec. 211.204 退货的药品

退货的药品应被标识和贮存。如果在退货药品退回之前或期间的保持，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

distribution of the batch.

(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.

(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.

(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.

(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:

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

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

(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.

significant step performed by the automated equipment.

(12) Any investigation made according to 211.192.

(13) Results of examinations made in accordance with 211.134.

[43 FR 45077, Sept. 29, 1978, as amended at 73 FR 51933, Sept. 8, 2008]

Sec. 211.192 Production record review.

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.

Sec. 211.194 Laboratory records.

(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:

(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.

(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

of complainant, nature of complaint, and reply to complainant.

(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).

(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.

[43 FR 45077, Sept. 29, 1978, as amended at 51 FR 24479, July 3, 1986; 68 FR 15364, Mar. 31, 2003]

Subpart K--Returned and Salvaged Drug Products

Sec. 211.204 Returned drug products.

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.

Sec. 211.208 Drug product salvaging.