

Food and Drug Administration, HHS

§211.1

- 211.82 Receipt and storage of untested components, drug product containers, and closures.
- 211.84 Testing and approval or rejection of components, drug product containers, and closures.
- 211.86 Use of approved components, drug product containers, and closures.
- 211.87 Retesting of approved components, drug product containers, and closures.
- 211.89 Rejected components, drug product containers, and closures.
- 211.94 Drug product containers and closures.

Subpart F—Production and Process Controls

- 211.100 Written procedures; deviations.
- 211.101 Charge-in of components.
- 211.103 Calculation of yield.
- 211.105 Equipment identification.
- 211.110 Sampling and testing of in-process materials and drug products.
- 211.111 Time limitations on production.
- 211.113 Control of microbiological contamination.
- 211.115 Reprocessing.

Subpart G—Packaging and Labeling Control

- 211.122 Materials examination and usage criteria.
- 211.125 Labeling issuance.
- 211.130 Packaging and labeling operations.
- 211.132 Tamper-evident packaging requirements for over-the-counter (OTC) human drug products.
- 211.134 Drug product inspection.
- 211.137 Expiration dating.

Subpart H—Holding and Distribution

- 211.142 Warehousing procedures.
- 211.150 Distribution procedures.

Subpart I—Laboratory Controls

- 211.160 General requirements.
- 211.165 Testing and release for distribution.
- 211.166 Stability testing.
- 211.167 Special testing requirements.
- 211.170 Reserve samples.
- 211.173 Laboratory animals.
- 211.176 Penicillin contamination.

Subpart J—Records and Reports

- 211.180 General requirements.
- 211.182 Equipment cleaning and use log.
- 211.184 Component, drug product container, closure, and labeling records.
- 211.186 Master production and control records.
- 211.188 Batch production and control records.
- 211.192 Production record review.
- 211.194 Laboratory records.

- 211.196 Distribution records.
- 211.198 Complaint files.

Subpart K—Returned and Salvaged Drug Products

- 211.204 Returned drug products.
- 211.208 Drug product salvaging.

AUTHORITY: 21 U.S.C. 321, 351, 352, 355, 360b, 371, 374; 42 U.S.C. 216, 262, 263a, 264.

SOURCE: 43 FR 45077, Sept. 29, 1978, unless otherwise noted.

Subpart A—General Provisions

§211.1 Scope.

(a) The regulations in this part contain the minimum current good manufacturing practice for preparation of drug products for administration to humans or animals.

(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.

(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 part 110 of this

§211.3

chapter, and where applicable, parts 113 to 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.

[43 FR 45077, Sept. 29, 1978, as amended at 62 FR 66522, Dec. 19, 1997; 69 FR 29828, May 25, 2004]

EFFECTIVE DATE NOTE: At 74 FR 65431, Dec. 10, 2009, §211.1 was amended by revising paragraph (a), effective Dec. 12, 2011. For the convenience of the user, the revised text is set forth as follows:

§211.1 Scope.

(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.

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§211.3 Definitions.

The definitions set forth in §210.3 of this chapter apply in this part.

Subpart B—Organization and Personnel

§211.22 Responsibilities of quality control unit.

(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.

(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.

(c) The quality control unit shall have the responsibility for approving or rejecting all procedures or specifications

21 CFR Ch. I (4–1–11 Edition)

impacting on the identity, strength, quality, and purity of the drug product.

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

§211.25 Personnel qualifications.

(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.

(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.

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

§211.28 Personnel responsibilities.

(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.

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