

§211.1

21 CFR Ch. I (4–1–08 Edition)

- 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 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]

§211.3 Definitions.

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