Subpart I—Packaging and Labeling

212.80 What are the requirements associated with labeling and packaging PET drug products?

Subpart J—Distribution

212.90 What actions must I take to control the distribution of PET drug products?

Subpart K—Complaint Handling

212.100 What do I do if I receive a complaint about a PET drug product produced at my facility?

Subpart L—Records

212.110 How must I maintain records of my production of PET drugs?


Source: 74 FR 65431, Dec. 10, 2009, unless otherwise noted.

Effective Date Note: At 74 FR 65431, Dec. 10, 2009, Part 212 was added, effective Dec. 12, 2011.

Subpart A—General Provisions

§ 212.1 What are the meanings of the technical terms used in these regulations?

The following definitions apply to words and phrases as they are used in this part. Other definitions of these words may apply when they are used in other parts of this chapter.

Acceptance criteria means numerical limits, ranges, or other criteria for tests that are used for or in making a decision to accept or reject a unit, lot, or batch of a PET drug product.


Active pharmaceutical ingredient means a substance that is intended for incorporation into a finished PET drug product and is intended to furnish pharmacological activity or other direct effect in the diagnosis or monitoring of a disease or a manifestation of a disease in humans, but does not include intermediates used in the synthesis of such substance.

Batch means a specific quantity of PET drug intended to have uniform character and quality, within specified limits, that is produced according to a single production order during the same cycle of production.

Batch production and control record means a unique record that references an accepted master production and control record and documents specific details on production, labeling, and quality control for a single batch of a PET drug.

Component means any ingredient intended for use in the production of a PET drug, including any ingredients that may not appear in the final PET drug product.

Conditional final release means a final release made prior to completion of a required finished-product test because of a malfunction involving analytical equipment.

Final release means the authoritative decision by a responsible person in a PET production facility to permit the use of a batch of a PET drug in humans.

Inactive ingredient means any intended component of the PET drug other than the active pharmaceutical ingredient.

In-process material means any material fabricated, compounded, blended, or derived by chemical reaction that is produced for, and is used in, the preparation of a PET drug.

Lot means a batch, or a specifically identified portion of a batch, having uniform character and quality within specified limits. In the case of a PET drug produced by continuous process, a lot is a specifically identified amount produced in a unit of time or quantity in a manner that ensures its having uniform character and quality within specified limits.

Lot number, control number, or batch number means any distinctive combination of letters, numbers, or symbols from which the complete history of the production, processing, packing, holding, and distribution of a batch or lot of a PET drug can be determined.

Master production and control record means a compilation of instructions containing the procedures and specifications for the production of a PET drug.

Material release means the authoritative decision by a responsible person in a PET production facility to permit the use of a component, container and
§ 212.2 What is current good manufacturing practice for PET drugs?

Current good manufacturing practice for PET drugs is the minimum requirements for the methods to be used in, and the facilities and controls used for, the production, quality assurance, holding, or distribution of PET drugs intended for human use. Current good manufacturing practice is intended to ensure that each PET 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 is supposed to have.

§ 212.5 To what drugs do the regulations in this part apply?

(a) Application solely to PET drugs. The regulations in this part apply only to the production, quality assurance, holding, and distribution of PET drugs. Any human drug that does not meet the definition of a PET drug must be manufactured in accordance with the current good manufacturing practice requirements in parts 210 and 211 of this chapter.

(b) Investigational and research PET drugs. For investigational PET drugs for human use produced under an investigational new drug application in accordance with part 312 of this chapter, and PET drugs produced with the approval of a Radioactive Drug Research Committee in accordance with part 361 of this chapter, the requirement under the act to follow current