

Subpart K—Complaint Handling

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

(a) *Written complaint procedures.* You must develop and follow written procedures for the receipt and handling of all complaints concerning the quality or purity of, or possible adverse reactions to, a PET drug product.

(b) *Complaint review.* The procedures must include review by a designated person of any complaint involving the possible failure of a PET drug product to meet any of its specifications and an investigation to determine the cause of the failure.

(c) *Complaint records.* A written record of each complaint must be maintained in a file designated for PET drug product complaints. The record must include the name and strength of the PET drug product, the batch number, the name of the complainant, the date the complaint was received, the nature of the complaint, and the response to the complaint. It must also include the findings of any investigation and followup.

(d) *Returned products.* A PET drug product that is returned because of a complaint or for any other reason may not be reprocessed and must be destroyed in accordance with applicable Federal and State law.

Subpart L—Records

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

(a) *Record availability.* Records must be maintained at the PET drug production facility or another location that is reasonably accessible to responsible officials of the production facility and to employees of FDA designated to perform inspections.

(b) *Record quality.* All records, including those not stored at the inspected establishment, must be legible, stored to prevent deterioration or loss, and readily available for review and copying by FDA employees.

(c) *Record retention period.* You must maintain all records and documentation referenced in this part for a period of at least 1 year from the date of final

release, including conditional final release, of a PET drug product.

PART 216—PHARMACY COMPOUNDING

Subpart A—General Provisions [Reserved]

Subpart B—Compounded Drug Products

Sec.

216.23 [Reserved]

216.24 Drug products withdrawn or removed from the market for reasons of safety or effectiveness.

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Subpart A—General Provisions [Reserved]

Subpart B—Compounded Drug Products

§216.23 [Reserved]

§216.24 Drug products withdrawn or removed from the market for reasons of safety or effectiveness.

The following drug products were withdrawn or removed from the market because such drug products or components of such drug products were found to be unsafe or not effective. The following drug products may not be compounded under the exemptions provided by section 503A(a) of the Federal Food, Drug, and Cosmetic Act:

Adenosine phosphate: All drug products containing adenosine phosphate.

Adrenal cortex: All drug products containing adrenal cortex.

Azaribine: All drug products containing azaribine.

Benoxaprofen: All drug products containing benoxaprofen.

Bithionol: All drug products containing bithionol.

Bromfenac sodium: All drug products containing bromfenac sodium.

Butamben: All parenteral drug products containing butamben.

Camphorated oil: All drug products containing camphorated oil.

Carbetapentane citrate: All oral gel drug products containing carbetapentane citrate.

Casein, iodinated: All drug products containing iodinated casein.