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Shipping chosen will not adversely affect the identity, purity, or quality of the PET drug product.

(b) Distribution records. You must maintain distribution records for each PET drug product that include or refer to the following:

(1) The name, address, and telephone number of the receiving facility that received each batch of a PET drug product;
(2) The name and quantity of the PET drug product shipped;
(3) The lot number, control number, or batch number for the PET drug product shipped; and
(4) The date and time you shipped the PET drug product.

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.

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216.24 Drug products withdrawn or removed from the market for reasons of safety or effectiveness.


SOURCE: 64 FR 10944, Mar. 8, 1999, unless otherwise noted.