**Section 725.70 Returned Drug Products**

Returned drug products shall be identified as such. If the conditions under which returned drug products have been held, stored, or shipped before or during their return, of if the condition of the drug products, its container, carton, or labeling, as a result of storage or shipping casts doubt on the safety, identity, strength, quality or purity of the drug product, the returned product shall be destroyed unless examination, testing, or other investigations prove the drug product meets appropriate standards of safety, identity, strength, quality, or purity as stated in 21 CFR 211. A drug product may be reprocessed provided the subsequent drug product meets appropriate standards, specifications, and characteristics as stated in 21 CFR 211. Records of return drug products shall be maintained and shall include the name and label potency of the drug product dosage form, lot number (or control number or batch number), reason for the return, quantity returned, date of disposition, and ultimate disposition of the returned drug product as stated in 21 CFR 211. Procedures for the holding, testing, and reprocessing of returned drug products shall be in writing and shall be followed.

(Source: Amended at 14 Ill. Reg. 864, effective January 1, 1990)