NOVA SOUTHEASTERN UNIVERSITY

Accountability of Investigational Products

Overview, Regulatory Support and References:

The steps involved in handling of study drug/devise include: receiving the drug from the Sponsor, acknowledging to the Sponsor the drug was received, storing the drug, properly dispensing the drug, documenting the quantity of the drug, returning the unused drug or destroying the unused drug.

- ICH Harmonized Tripartite Guideline E6: Good Clinical Practice:
- Poison Prevention Protection Act (15 U.S.C. 1471-1476) (Public Law 91-601, 84 Stat. 1670, December 30, 1970, as amended)
- Title 16--Commercial Practices / CHAPTER II--CONSUMER PRODUCT SAFETY COMMISSION/PART 1700--POISON PREVENTION PACKAGING
- 21 CFR 312.59
- 21 CFR 312.61
- 21 CFR 312.69

U.S. Consumer Product Safety Commission June 22,2000 Letter to Canon Communications, LLC "RE: Drugs dispensed for household use in clinical trials" (http://www.cpsc.gov/BUSINFO/trials.pdf)