FAQ: How should I record investigational agents that come in oral dosage forms?

There are two things to consider:

(1) If the protocol includes a statement indicating you must “dispense the product in its original bottle,” in the pharmaceutical section, you will have to use the bottles as they are. It’s easiest to dispense full bottles, and record them on the Drug Accountability Record Form as whole bottles. If the original bottle does not have a child-proof cap, then place the original bottle into a child-proof vial. This will maintain agent integrity.

(2) If there is no instruction to dispense from its original bottle, then the decision rests with you.

- If you are going to dispense only the amount needed from its original bottle, indicate how many dosage units you have dispensed, and maintain a running balance of tablets or capsules remaining.
- If you are going to dispense full bottles, keep a running total of how many bottles remain in your inventory.

Just be consistent with your procedure when you log-in/out from the Drug Accountability Record. And, make sure that you have the appropriate auxiliary labels (e.g., For Investigational Use Only).

September 11, 2008