From: OC GCP Questions
To: [redacted]
Subject: IP return
Date: Thursday, January 26, 2017 6:47:00 AM

Good morning --

Please see the information below regarding return of unused IP.

Regarding record keeping requirements for sponsors and investigators there are three references which are pertinent to the topic of records of investigational drug disposition and use. Sponsor requirements in this area are found at 21 CFR 312.59 and 312.57. 21 CFR 312.62 pertains to the clinical investigator.

312.59. This section deals with disposition of unused supply of investigational drug and makes the sponsor responsible for ensuring the return of unused supplies from the sites or authorizing alternate disposition which does not expose humans to risks from the drug. This section requires the sponsor to maintain records of the disposition in accordance with 312.57.

312.57(a) states, "A sponsor shall maintain adequate records showing the receipt, shipment, or other disposition of the investigational drug. These records are required to include, as appropriate, the name of the investigator to whom the drug is shipped, and the date, quantity, and batch or code mark of each such shipment." This requirement when applied to the return of unused supplies would require that the sponsor maintain a record of receipt of unused supplies returned from the site. In practice, most sponsors do maintain documentation to show both the shipment and return of drugs. Such documentation often includes packing lists, common carrier forms and internally generated documents such as memo accounting for the inventory.

21 CFR 312. 62(a) pertains to disposition of drug at the clinical site and states, " An investigator is required to maintain adequate records of the disposition of the drug, including dates, quantity, and use by subjects. If the investigation is terminated, suspended, discontinued, or completed, the investigator shall return the unused supplies of the drug to the sponsor, or otherwise provide for disposition of the unused supplies of the drug under sec. 312.59". The regulation seems to imply that that clinical investigator should maintain records showing disposition of the drug returned to the sponsor. These records would typically include records of shipment of unused supplies back to the sponsor. Such records could include for example, common carrier shipping records, a drug log or other inventory records such as memos to the file. The clinical investigator only has to keep a record showing the drug was returned. There is no explicit regulatory requirement that the clinical investigator must confirm receipt by the sponsor and keep a record of this at the clinical site. Logically, the sponsor should have a record of the return as explained above and required under 312.57. This would seem to address the concern that there is some record to confirm final receipt of drug returned from the sites.

Documentation of the unused product should be completed and the unused IP should be returned to the sponsor.

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

This communication does not constitute a written advisory opinion under 21 CFR 10.85, but rather is an informal communication under 21 CFR 10.85(k) which represents the best judgment of the employee providing it. This information does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

-----Original Message-----
From: [redacted]
Sent: Tuesday, January 24, 2017 7:17 PM
To: OC GCP Questions
Subject: IP return

Hello,
Will you please tell what the FDA requirement is on IP verification when a subject returns an IP bottle.

For example subject xyz returns an IP bottle that contains four pills. The site coordinator verifies that four pill are in the bottle. Is it expected that the monitor verifies that there are four pills or just verifies that the documentation has been completed?

Thank you
[redacted]