From: OC GCP Questions
To: [redacted]
Subject: shipping investigational product question
Date: Wednesday, June 17, 2015 3:31:04 PM

Good afternoon –

I consulted with the Center for Drugs (CDER) and we think the scenario you describe may not be in compliance with FDA regulations. FDA CDR 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."

Additionally FDA CFR 312.62 (a) states – "Disposition of drug. 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 312.59."

The investigational product should be labeled. CDER recommends that you and or the sponsor/physician contact the regulatory project manager (RPM) of the IND at FDA for guidance. It is best to document the directions that are given to you by FDA.

I hope this information is helpful. Please contact us again at gcp.questions@fda.hhs.gov should you have additional GCP questions.

For specific drug questions, please see CDER direct contact information below.

Questions about drug products (other than gcp questions)
301-796-3400
Druginfo@fda.hhs.gov
Questions about whether a product is subject to IND regulations: call 301-796-3400

Kind regards,

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

From: [redacted]
Sent: Monday, June 15, 2015 4:44 PM
To: OC GCP Questions
Subject: shipping investigational product question

Good afternoon,

I am a pharmacist working on a clinical trial where one of our physicians has obtained an IND for a medication and is conducting a Phase II clinical trial at our site and he plans to open a secondary research site at another facility out of state. We are being asked to ship IP to the secondary research site and I want to make sure we are complying with all existing regulations in doing this. My question is two-fold:

1. This IP came to us from a drug company unlabeled, so there is no indication of drug name, strength, expiration, or the "Caution: New Drug--Limited by Federal (or United States) law to investigational use." statement. We basically determine what it is by comparing the lot number printed on the bottle to the shipping invoice that accompanied the shipment. We currently apply a standard prescription label to each container when it is dispensed to a subject that contains all of this information. Is there anything prohibiting me from applying a label that our site would make to each of the bottles prior to shipping the medication to the secondary research site, since we have paperwork from the drug company that indicates what is in each container? The drug company states that they are unable to provide us with labels to apply to the containers that would better indicate what is in the bottle.
2. Is there any regulation prohibiting the drug company from sending us unlabeled bottles?

Thank you in advance for any assistance you might provide. If you think that another department might be more appropriate to assist me in this query, please let me know and I would be happy to contact them.

Sincerely,

[redacted]