From: OC GCP Questions
To: [redacted]
Subject: Seeking guidance on Investigational drug product
Date: Wednesday, November 19, 2014 2:29:35 PM

Good afternoon --

It is not against FDA regulations that a subject be sent home with a pill bottle. However, again I cannot specifically answer your question as I don't know your IP. You should ask the sponsor of your study.

That said, please see a few guidance document links below as well as the FDA regulation -- Sec. 312.6 Labeling of an investigational new drug.

There is guidance regarding packaging and labeling of investigational drugs products.

ICH E6
(
http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM073122.pdf
) states the following:

5.13 Manufacturing, Packaging, Labeling, and Coding Investigational Product(s)
5.13.1 The sponsor should ensure that the investigational product(s) (including active comparator(s) and placebo, if applicable) is characterized as appropriate to the stage of development of the product(s), is manufactured in accordance with any applicable GMP, and is coded and labeled in a manner that protects the blinding, if applicable. In addition, the labeling should comply with applicable regulatory requirement(s).

In regards to investigational products, drugs that are used in IND studies are required be labeled in accordance with 21 C.F.R. § 312.6, including the statement "Caution: New Drug – Limited by Federal (or United States) to investigational use" and must not bear any false or misleading statement. [See: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.6]

Kind regards,

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

From: [redacted]
Sent: Wednesday, November 19, 2014 1:54 PM
To: OC GCP Questions
Subject: Re: Seeking guidance on Investigational drug product

Thank you for the response.

Would you please provide the FDA requirements for labeling of the investigational product bottles that is dispensed to patients during their study visits? Patients will be sent home with

their treatment in the form of capsules in a bottle.

Thank you.
[redacted]

On Nov 19, 2014, at 11:39 AM, OC GCP Questions <gcp.questions@fda.hhs.gov> wrote:

> Good morning –
>
> I am sorry I cannot specifically answer your questions regarding your investigational product labeling and bottling. It is best to contact FDA's program manager for your IND and ask his/her these questions as they will be very familiar with your IP.
>
> 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.
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>
> **From:** [redacted]
> **Sent:** Tuesday, November 18, 2014 10:40 PM
> **To:** OC GCP Questions
> **Subject:** Seeking guidance on Investigational drug product
>
> Dear FDA,
>
> Would you please provide guidance on the following questions regarding investigational product. This is being considered for a phase 1 oncology study for patients who will take their first dose in the hospital/clinic and subsequent doses at home until they return for their next study visit.
>
> Question 1:
>
> The investigational product for a study will be shipped by the manufacturer with labels that are compliant with the regulations outlined in FDA Regulations (CFR 312), which are received by the pharmacist at each participating site. Once a patient is enrolled, the pharmacy will then dispense the investigation product according to the treatment assignment. In doing so, the pharmacist will remove the prescribed amount of product from the original container and transfer the amounts into a separate, "secondary" container, but the pharmacist will then also generate a label according to the standards set by the individual hospital/pharmacy SOPs.

Under such circumstances, does the pharmacy generated label applied to this secondary container require the same labeling requirements as the original bottles?

Quesion 2:

Is it acceptable for the 'secondary' container to be the typical amber bottles used by pharmacies, and is there any requirements to conduct stability on these amber bottles? The study drug capsules require refrigeration. Amber bottles size used by the pharmacy will depend on the number of capsules/dose, hence minimizing oxygen overlay.

Question 3:

Is it acceptable to dispense study drug in one bottles containing two different strengths? Each bottle of study drug will contain a single dose that may contain for example, two 50mg capsules, and one 10mg capsule, based on body weight. Patients will be provided 3 bottles and instructed to take the entire contents of each bottle on 2 dosing days. The third study drug bottle is being provide as a precaution in case of inadvertent loss or missed study visit.

I appreciate your guidance.

Thank you.

[redacted]