From: OC GCP Questions
To: [redacted]
Subject: Dietary Supplement/Finished Product
Date: Thursday, April 02, 2015 11:02:52 AM

Good morning [redacted]--

I checked with a few colleagues in my office. Please keep in mind that we generally answer questions related to FDA-regulated studies or studies under IND/IDE only. Please see the general information related to labeling below.

If the study isn't going to be a blinded study there would need to be the standard type of information that would be included on a prescription bottle. There would need to be information about the patient, the directions for use, the product contained in the bottle, the date it was filled, expiration date, and the prescriber's information. This would likely be determined under state law. Since you are transferring the product to a different container, you would probably need to keep information about which product you used and what lot numbers are involved.

Even if it was a blinded study, there would need to be some type of information so that the investigators can trace the product back in the event of a recall or something.

As mentioned, it would be a matter of what would be required by the state.

Kind regards,

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

From: [redacted]
Sent: Wednesday, April 01, 2015 7:10 AM
To: OC GCP Questions
Subject: Dietary Supplement/Finished Product

Good morning,

I've been asked by the FDIC to contact your office about a question that we have (see the email below):

We are giving a vitamin supplement to our test subjects. The supplements are bought from a store that anybody can buy and consume, i.e. off-the-shelf without a prescription. We will

be transferring the vitamins to a generic bottle which we will give to the test subjects. Does the bottle need any specific labeling? This is not a drug study. It is also not an IND study.

Thank you for your help with this.

Regards,

[redacted]