From: OC GCP Questions
To: [redacted]
Subject: Labels for investigational Products
Date: Monday, April 27, 2015 10:09:24 AM

Good morning –

Labeling of an investigational product can be found und 21 CFR 312.6. See below.

CFR - Code of Federal Regulations Title 21

Sec. 312.6 Labeling of an investigational new drug.
(a) The immediate package of an investigational new drug intended for human use shall bear a label with the statement "Caution: New Drug--Limited by Federal (or United States) law to investigational use."

(b) The label or labeling of an investigational new drug shall not bear any statement that is false or misleading in any particular and shall not represent that the investigational new drug is safe or effective for the purposes for which it is being investigated.

(c) The appropriate FDA Center Director, according to the procedures set forth in 201.26 or 610.68 of this chapter, may grant an exception or alternative to the provision in paragraph (a) of this section, to the extent that this provision is not explicitly required by statute, for specified lots, batches, or other units of a human drug product that is or will be included in the Strategic National Stockpile.

Additionally, 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. If 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. .

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

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

Kind regards,

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

From: [redacted]
Sent: Friday, April 24, 2015 1:59 PM
To: OC GCP Questions
Subject: Labels for investigational Products

Dear Office of GCP,
Are there requirements for what information must be included on a label that will be placed on an investigational product that will be used in a clinical trial. If so, where can I find those requirements.

Thank you in advance for your assistance.

[redacted]