From: OC GCP Questions
To: [redacted]
Subject: IND Product Labeling
Date: Tuesday, July 11, 2017 9:33:00 AM
Attachments: [redacted]

Good morning –

I strongly suggest if the study is under IND that you contact the appropriate FDA review division as the division may have other suggestions on what needs to be included on the investigational product label. As a rule of thumb, the label of an IND drug product should comply with the general labeling requirements under 21 CFR 201.1. It may also need to comply with other requirements such as 21 CFR 201.17 (lot no.) and 201.18 (exp. date). The labeling will also need to comply with state and local laws where the research is being conducted.

Additionally, the best guidance to reference re: the preparation (and labeling) of investigational new drug products is entitled "Guideline on the Preparation of investigational New Drug Products". This guidance can be found on the Center for Drug Evaluation and Research "guidance" web page (www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm070315.pdf). To paraphrase, this guidance states that CGMPs apply to for the preparation of new drug substances or drug products when the drug products are produced for clinical trials in humans. On page 6 of this guidance, you can find information about packaging and labeling operations. This basically states CGMP sections governing packaging and labeling operations apply to investigational drug products. Based on labeling regulations found elsewhere as you state at 21 CFR 312.6, certain labeling information may be provided separately from the drug container. The one example provided in the guidance is the use of lot or control numbers; these can be provided separately in a code-breaking guide furnished to the clinical investigator vs. putting the information directly on the product container label.

If you cannot contact the FDA review division or project manager of the IND, I suggest contacting the Center for Drugs (CDER) at druginfo@fda.hhs.gov for additional guidance as they specifically answer IND questions.

Kind regards,

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

FDA U.S. FOOD & DRUG ADMINISTRATION

From: [redacted]
Sent: Monday, July 10, 2017 1:44 PM
To: OC GCP Questions
Subject: IND Product Labeling

A firm with whom I am working is trying to resolve an internal disagreement regarding the need to display the clinical trial study number on the immediate container of an investigational product. The person who believes this is necessary cites 21 CFR 312.6 as the basis.

I see no requirement for labeling the immediate container of an IND product with the clinical study number in the cited regulation or elsewhere in 21 CFR 312.

FYI, the product in question is stored frozen, and the immediate container must be brought into an operating room and opened under aseptic conditions in the OR.

Do you concur that the regulations do not require the presence of the clinical study number on the immediate container of an IND product?