From: OC GCP Questions
To: [redacted]
Subject: Labelling of IMPs for BE studies
Date: Wednesday, May 21, 2014 8:59:54 AM

Good morning –

FDA's 320 regulations do not require that the protocol number be on the IMP for BE studies. The regulations (link below) only address labeling related to active ingredients of the investigational product. When the regulations are silent, sites and institutions are free to develop their own standard operating procedures (SOPs) to address a particular situation or issue.

CFR - Code of Federal Regulations Title 21

It would be helpful for you to review FDA's guidance on BE/BA studies. See the link below.

http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM227351.pdf

If I have not adequately answered your question please contact the Center for Drugs (CDER) directly at druginfo@fda.hhs.gov.

Kind regards,

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

From: [Redacted]
Sent: Wednesday, May 21, 2014 7:22 AM
To: OC GCP Questions
Subject: Labelling of IMPs for BE studies

Dear Sir, Madam

Could you please inform of the FDA expectations regarding labelling of IMPs for bioequivalence studies with regards providing the protocol number.
If it is the FDA expectation that protocol number should be provided on the IMP label, would it be acceptable to list 2 protocol numbers, in case of Fed and Fasting BE studies.

Thank you

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