From: OC GCP Questions
To: [redacted]
Subject: question
Date: Monday, March 23, 2015 11:50:41 AM

Good morning –

I am not very familiar with BA/BE studies (CFR 320 regs) so it is probably best to contact the Center for Drugs (CDER) Office of Bioequivalence. Please see their website link below.

About the Center for Drug Evaluation and Research > Office of Generic Drugs: Offices and Divisions

You can also email CDER at druginfo@fda.hhs.gov or the Office of Generic Drugs at GCDRequest@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: Saturday, March 21, 2015 2:11 PM
To: OC GCP Questions
Subject: question

Dear Doreen,
I have a regulatory question. I hope I am asking the question correctly. Please answer at your convenience.

- For every phase I study, specifically a bio-equivalence study, is there supposed to be a medical monitor available or someone from the sponsor's side available at all times?

Thank you for your reply.

[redacted]