From: OC GCP Questions
To: [redacted]
Subject: Conducting small clinical trial using old drug for new target
Date: Wednesday, June 20, 2018 5:57:42 AM

Good morning –

Most likely you will need to supply more information. However, you will have to contact the Center for Drugs (CDER) directly at druginfo@fda.hhs.gov

Kind regards,

The OGCP Group

From: [redacted]
Sent: Wednesday, June 20, 2018 1:17 AM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: Conducting small clinical trial using old drug for new target

Are there any required governmental approvals to be secured before initiating a clinical trial repurposing an old, safe, established drug?

Please advice on what steps to take if any regulatory registration and approval for such study is necessary.

Thank you for your help and guidance.

[redacted]