From: OC GCP Questions
To: [redacted]
Subject: Inquiry about Pharmacovigilance activites-reg
Date: Wednesday, June 11, 2014 8:38:37 AM

Good morning –

This is a general good clinical practice mailbox. It is best to send your question to the Center for Drugs (CDER) 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: [redacte]
Sent: Wednesday, June 11, 2014 1:29 AM
To: OC GCP Questions
Subject: Inquiry about Pharmacovigilance activites-reg

Dear FDA,

Greetings from India!

My name is [redacted] and I am a clinical researcher since 2009.

I have little confusion with respect to the pharmacovigilance activities in Clinical Trials for concomitant drugs or co-suspect drugs or drug used in response to the adverse event or adverse drug reaction.

Moreover I would also like to clear if the company has got the authorization of the XYZ drug molecule but not commercialized. The same drug molecule XYZ is being used in clinical trial as a non-investigation drug by some company.

What are the responsibilities involved for the company who has only authorized the drug molecule but not commercialized?

Thank you
[redacted]