From: OC GCP Questions
To: [redacted]
Subject: About the reference drug for clinical trials in order to get FDA approval
Date: Thursday, January 09, 2014 8:16:02 AM

Good morning –

For answer to your questions, you will need to contact the Center for Drugs (CDER) directly at druginfo@fda.hhs.gov or by phone 1-888-463-6332. They most likely will refer you to one of their review divisions to answer your questions.

Kind regards,

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

From: [Redacted]
Sent: Wednesday, January 08, 2014 9:25 PM
To: OC GCP Questions
Subject: About the reference drug for clinical trials in order to get FDA approval

Dear FDA People,
Hello. Happy new year.
I am _____ working for a pharmaceutical company, _____.
I am contacting you for one question.
(I have already searched FDA website to find a guideline but unfortunately I couldn't find the proper answer for that)

Now we are planning of clinical development of our Product, _____ combination for osteoporosis treatment for FDA approval.
Do you have any guideline for choosing the reference drug for phase I study.
Dose the reference drug have to be a marketed product in USA? (Is that acceptable the reference drug is marketed in EU.)
I know you must be very busy but if you give me some tips for that I would very much appreciate for that.
I look forward to hearing from you.
Thank you.
[redacted]