

**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

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Good morning –

For answer to your questions, you will need to contact the Center for Drugs (CDER) directly at [druginfo@fda.hhs.gov](mailto: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,

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Senior Health Policy Analyst  
Office of Good Clinical Practice  
Office of the Commissioner, FDA

This communication does not constitute a written advisory opinion under 21 CFR 10.85, but rather is an informal communication under 21 CFR 10.85(k) which represents the best judgment of the employee providing it. This information does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

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**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 [REDACTED] working for a pharmaceutical company, [REDACTED].  
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, [REDACTED] 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]