From: OC GCP Questions
To: [redacted]
Subject: [redacted]
Date: Wednesday, May 20, 2015 11:42:59 AM

Good morning –

Please contact the Center for Drugs (CDER) at druginfo@fda.hhs.gov. They will likely refer your question to one of the review divisions. I am not sure if the Office of Orphan Products will be helpful to you. However below is their website link.

Office of Special Medical Programs > Office of Orphan Products Development

I hope this information is helpful. Please contact us again at gcp.questions@fda.hhs.gov should you have additional questions.

Kind regards,

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

From: [redacted]
Sent: Tuesday, May 19, 2015 5:11 PM
To: OC GCP Questions
Subject: [redacted]

Dear FDA GCP folks,
Can you give me the name and contact information for an FDA person who can discuss with me a potential request for a radioactive drug [redacted] to be used for carcinoid patients by a carcinoid expert who is interested in its non-research treatment use in a terminal and willing patient under the state's right to try law. It is currently listed as an unapproved orphan drug if I am reading the info correctly at http://www.fda.gov/downloads/forindustry/developingproductsforrarediseasesconditions/howtoapplyfororphanproductdesignation/ucm162066.xls
I realize FDA considers the use of any unapproved product as a "clinical investigation" that requires an IND (or RDRC in some cases) and IRB approval. Now that so many states have passed right to try laws for terminal patients, does FDA allow enforcement discretion in these types of cases? Or is the traditional position still taken of an IND is required? Does FDA expedite and make simple the compassionate treatment use of [redacted] , and if so who do I get the interested physicians in contact with? What is likely to happen in practice if the physician and terminal patient opt to bypass the FDA/IRB based on the state right to try law if they feel the burden of obtaining an IND/IRB approval is too time consuming?

Thanks
[redacted]