**From:** OC GCP Questions
**To:** [redacted]
**Subject:** USA label requirement for Radioactive product for Clinical trial
**Date:** Monday, June 15, 2015 1:30:09 PM

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Good afternoon –

My office cannot specifically answer your question. However I did find a web link at FDA and a guidance on radioactive product. The first link provides a second link (last one on the list) "Contact us" that you can send your question to. It brings you to an email account. RDRC@cder.fda.gov. The second link is the guidance.

Oncology > Radioactive Drug Research Committee (RDRC) Program

http://www.fda.gov/downloads/Drugs/Guidances/UCM163892.pdf
I hope this information is helpful.

Kind regards,

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



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**From:** [redacted]
**Sent:** Monday, June 15, 2015 11:34 AM
**To:** OC GCP Questions
**Subject:** USA label requirement for Radioactive produt for Clinical trial

Hi,

My name is [redacted], I work for a CRO company and I would like to know if you can provide a guidance or any information for USA Label requirement for Radioactive material during the clinical trial.

Thank you so much.

Kind regards,

[redacted]