



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

February 16, 2012

Deepika Jalota, PharmD
Bayer HealthCare Pharmaceuticals
P.O. Box 1000
Montville, New Jersey 07045
Email: deepika.jalota@bayer.com

Dear Ms. Jalota:

I am writing in response to our meeting on February 14, 2012, regarding the medical use of Radium-223 (Ra-223) chloride. I appreciate Bayer sharing information on the potential commercial use of this product in the U.S. The presentations by Dr. Garcia-Vargas, Dr. Gay, and Dr. Siegel were very informative, and Dr. Biggin and many of the individuals from Bayer were helpful in answering staff's questions. The NRC staff gained a better understanding of the clinical and radiation safety aspects of Ra-223 chloride for the treatment of late-stage castration-resistant prostate cancer with bone metastases. As discussed, NRC staff will share this information with the U.S. NRC's Advisory Committee on the Medical Uses of Isotopes (ACMUI), and we look forward to continued dialogue at the ACMUI public meeting in April.

Sincerely,

A handwritten signature in black ink, appearing to read "CE Einberg", is written over the typed name and title.

Christian E. Einberg
Chief, Radioactive Materials
Safety Branch
Division of Materials Safety and
State Agreements
Office of Federal and State Materials
and Environmental Management
Programs