

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: <u>deepika.jalota@bayer.com</u>

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

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