Norwalk
Hospital

Norwalk,
Connecticut 06856

May 23, 2013

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03001267

REC.RG1 06/18/13 AM 07:19

Balan Kodery, MS
Radiation Safety Officer
Department of Radiation Oncology
Norwalk Hospital
24 Stevens Street
Norwalk, CT 06856

USNRC
Commercial and R&D Branch
Division of Nuclear materials safety
Region 1
~~475 Allendale Road~~ 2100 Renaissance Blvd, Suite 100
King of Prussia
Pennsylvania, 19406-~~1415~~ 2713

License Number 06-06941-01
Docket # 03001267

Sub: License Amendment Request

Dear Sir/Madam,

Norwalk hospital would like to use Radium 223 Dichloride for therapeutic use given to each patient at 4 week intervals for 6 injections for treatment of patients with symptomatic bone metastasis.

We request you to amend our license incorporating the use of the following isotope:

1. Ra 223 Dichloride Maximum quantity: 1.0 mCi.

581170

NMSS/RGN1 MATERIALS-002

Chemical and physical form of the above isotope:

Radium 223 Dichloride in single use unit dose vials in 6 ml of solution for IV injections.

Proposed Authorized User: Edward Strauss. M. D.
Dr. Strauss is authorized in our license for 35.300 materials

Kindly amend the license incorporating the requested change and mail us a copy of the amended license.

Sincerely,

Balachandran Kodery

Balachandran Kodery, MS
Radiation safety officer

En: Brochure for Radium 223 Dichloride.

RADIATION SAFETY PRACTICES

Radium Ra 223 dichloride (radium 223 dichloride) should be received, used, and administered only by persons authorized to handle radiopharmaceuticals in designated clinical settings. The receipt, storage, use, transfer, and disposal of the drug are subject to regulation by the Nuclear Regulatory Commission or applicable Agreement State authorities, as well as specific facility license requirements. Radium 223 dichloride should be handled by the user in a manner that satisfies both radiation safety and pharmaceutical quality requirements. Appropriate aseptic precautions should be taken.

HOW SUPPLIED

Treatment sites will receive a unit dosage in a syringe prepared by a commercial radiopharmacy.

A commercial radiopharmacy will be supplied with Radium 223 dichloride in single use vials containing 6 mL of solution (1000 kBq/mL, 0.027 mCi/mL) at the reference date.[1] Radium 223 dichloride is a ready-to-use solution and should not be diluted or mixed with any solutions. The drug is supplied in a Type A-certified package containing:

- Shielding container
- Certificate of Analysis
- Decay correction table according to physical decay of Ra 223

MEASUREMENT OF RADIOACTIVITY USING STANDARD INSTRUMENTS

The radioisotope Ra 223 is primarily an alpha emitter; however, beta particles and photons are also emitted during decay. The photons allow for measurement of radioactivity with standard instruments such as a dose calibrator and standard gamma detectors.

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This is to acknowledge the receipt of your letter/application dated

05-23-13, and to inform you that the initial processing which includes an administrative review has been performed.

Amend: 06-06941-01

☑ There were no administrative omissions. Your application was assigned to a technical reviewer. Please note that the technical review may identify additional omissions or require additional information.

☐ Please provide to this office within 30 days of your receipt of this card

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A copy of your action has been forwarded to our License Fee & Accounts Receivable Branch, who will contact you separately if there is a fee issue involved.

Your action has been assigned **Mail Control Number** 581170.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.

NRC FORM 532 (RI)
(6-96)

Sincerely,
Licensing Assistance Team Leader