UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
2100 RENAISSANCE BOULEVARD, SUITE 100
KING OF PRUSSIA, PA 19406-2713

April 11, 2014

Docket No. 03036911 License No. 52-25430-03
Control No. 582868

David Rhoe
President
CRMI
D-4 Calle Tivoli
Paseo de La Fuente
San Juan, PR 00926-6459

SUBJECT: CRMI, AMENDMENT NOT NEEDED AND CORRECTED COPY OF LICENSE, CONTROL NO. 582868

Dear Mr. Rhoe:

In your letter dated December 30, 2013, you requested clarification of Radium-223 dichloride ($^{223}RaCl2$) use. Please note that the Advisory Committee for Medical Uses of Isotopes (ACMUI) issued a report dated November 20, 2012 (ML12326A568) addressing the use of $^{223}RaCl_2$. Based on the ACMUI recommendation, on January 10, 2013, the Nuclear Regulatory Commission issued FSME-13-002 Notice of Licensing Decision on Radium-223 Dichloride (ML13008A149) documenting the licensing decision.

The ACMUI report suggested that, even though $^{223}RaCl_2$ and its progeny emit 95%, 4%, and 1% of their total radiation energy in the form of alpha particles, beta particles, and x- and gamma-rays, respectively, $^{223}RaCl_2$ does not differ fundamentally from current routinely used therapeutic radiopharmaceuticals. The ACMUI further stated that Category 3 [10 CFR 35.390(b)(1)(ii)(G)(3)], which applies to "Parenteral administration of any beta emitter, or a photon- emitting radionuclide with a photon energy less than 150 keV, for which a written directive is required"; does not explicitly include or exclude alpha-particle emitters. Since ^{223}Ra progeny emit beta particle, as well as alpha particles, the ACMUI stated that $^{223}RaCl_2$ technically might be considered a "Category (3)" radiopharmaceutical. NRC staff agreed with the ACMUI recommendation and determined that licensing under 10 CFR Part 35, Subpart E is appropriate because the medical use of $^{223}RaCl_2$ is similar to other commonly used beta and photon-emitting therapeutic radiopharmaceuticals. In addition, physicians who are approved for the use of any beta emitter or any photon-emitting radionuclide with a photon energy less than 150 keV under 10 CFR 35.390 or 10 CFR 35.396 may be authorized for the medical use of $^{223}RaCl_2$. Therefore, if a license already authorizes full use under 10 CFR 35.300 and has authorized users authorized for either all of 35.300 materials or Parenteral administration of any beta emitter, or a photon-emitting radionuclide with a photon energy less than 150 keV, then an amendment is not needed. Physicians authorized for the use of sodium iodide I-131 under 10 CFR 35.392 and/or 10 CFR 35.394 are not authorized for the use of $^{223}RaCl_2$. In order for these individuals to be authorized for $^{223}RaCl_2$ use, they need to document 200 hours of training and experience required by 35.390(b)(1) and a minimum of three cases of parenteral administration of any beta emitter, or photon-emitting radionuclide with a photon energy less than 150 keV, for which a written directive is required. The three cases may be with samarium-153, $^{223}RaCl_2$, or any other

radiopharmaceutical that falls under parenteral administration of any beta emitter, or photon-emitting radionuclide with a photon energy less than 150 keV.

In addition, during an administrative review of your license, it was identified that the authorized use for Sandra C. Gracia-Lopez, M.D. was incorrectly stated as 35.30. This error has been corrected to read as 35.300.

Current NRC regulations and guidance are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Med, Ind, & Academic Uses;** then **Licensee Toolkits, see our toolkit index page.** You may also obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-866-512-1800. The GPO is open from 8:00 a.m. to 5:30 p.m. EST, Monday through Friday (except Federal holidays).

Thank you for your cooperation.

Sincerely,

Original signed by James P. Dwyer

James P. Dwyer, Chief
Medical Branch
Division of Nuclear Materials Safety

Enclosure:
Corrected Copy of Amendment No. 5

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SUNSI Review Complete: TWeidner

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