



UNITED STATES
NUCLEAR REGULATORY COMMISSION

REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, ILLINOIS 60532-4352

FEB 12 2013

Christopher J. Conlin, M.D.
Radiation Safety Officer
McLaren – Flint
401 South Ballenger Highway
Flint, MI 48532

Dear Dr. Conlin:

This refers to your December 21, 2012 request to amend your license for the use of unsealed therapeutic dosages of $^{223}\text{RaCl}_2$. Note that, on January 10, 2013, the Nuclear Regulatory Commission issued a letter to Bayer HealthCare Pharmaceuticals, Inc. ("Bayer letter"; ML12349A275). The Bayer letter confirmed that the use of $^{223}\text{RaCl}_2$, as requested and described in your letter, is authorized for entities authorized for 10 CFR 35.300 radioactive materials use, as described in Title 10 of the Code of Federal Regulations (CFR), Subpart E, "Unsealed Byproduct Material – Written Directive Required".

The most recent amendment to your license, NRC license 21-04171-04 already authorizes the use of radioactive materials under 10 CFR 35.300. Therefore, your license need not be amended at this time to permit the medical use of $^{223}\text{RaCl}_2$.

In addition, as described in the Bayer letter, all Authorized Users (AUs) currently 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, 'Training for use of unsealed byproduct material for which a written directive is Required,' or 10 CFR 35.396, 'Training for the parenteral administration of unsealed byproduct material requiring a written directive,' are authorized for the medical use of $^{223}\text{RaCl}_2$.

Since your license already lists several AUs with 10 CFR 35.300 authorizations including, "any beta emitter or any photon-emitting radionuclide with a photon energy less than 150 keV", no amendment is needed to permit those AUs for use of therapeutic dosages of $^{223}\text{RaCl}_2$. We have voided your request accordingly. If you have any questions or require clarification on any of the information stated above, you may contact us at (630) 829-9887.

The NRC's Safety Culture Policy Statement became effective in June 2011. While a policy statement and not a regulation, it sets forth the agency's *expectations* for individuals and organizations to establish and maintain a positive safety culture. You can access the policy statement and supporting material that may benefit your organization on NRC's safety culture Web site at <http://www.nrc.gov/about-nrc/regulatory/enforcement/safety-culture.html>. We strongly encourage you to review this material and adapt it to your particular needs in order to develop and maintain a positive safety culture as you engage in NRC-regulated activities.

C. Conlin, M.D.

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In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>.

Sincerely,

A handwritten signature in black ink that reads "Sara A.B. Forster". The signature is written in a cursive style with a large initial 'S'.

Sara A.B. Forster, M.S.
Health Physicist
Materials Licensing Branch

License No. 21-04171-04
Docket No. 030-02048