



FLINT

**RADIOLOGY**

401 South Ballenger Highway  
Flint, Michigan  
48532-3638

tel (810) 342 2209  
fax (810) 342 2100

**mclaren.org**

December 21, 2012

U.S. Nuclear Regulatory Commission  
Region III  
Materials Licensing Section  
2443 Warrenville Road  
Suite 210  
Lisle, Illinois 60532-4351

Dear Sir/Madam:

We wish to amend our Materials License #21-04171-04, McLaren Flint as follows:

**ADD – AUTHORIZED USE AND POSSESSION**

<b><u>Byproduct Material</u></b>	<b><u>Form or Manf / Model #</u></b>	<b><u>Max. Quantity</u></b>	<b><u>Authorized Use</u></b>
Radium-223	Chloride Aqueous Injectable Solution	5 mCi	Radiopharmaceutical Therapy - Written Directive Required

We wish to add Radium-223 Chloride as a sterile aqueous solution for intravenous injection for treatment of patients with late-stage castration-resistant prostate cancer with bone metastases. We wish to participate in a clinical trial of this radiopharmaceutical know as “Alpharadin” as supplied by Bayer HealthCare AG under a company sponsored IND #067521.

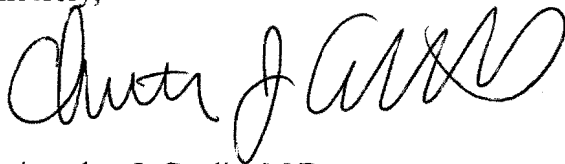
- We confirm that all aspects of our “Radiation Protection Program”, to include receipt, use and disposal will be applied to this clinical usage.
- We confirm that all aspects of our “Written Directive Program”, to include “Patient Release” will be applied to this radiopharmaceutical usage.
- The manufacture will supply radiation safety training to include question and answers specific to this product, to technical and physician staff prior to first patient use.

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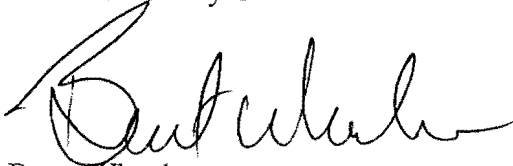
- The manufacturer will initially proctor at least the first three (3) clinical cases for authorized users as a "Preceptor" for this specific radiopharmaceutical.
- Dose calibrators will be calibrated with NIST traceable standards prior to first patient use.

If you have any questions regarding this request, please contact Arthur Ewald at (810) 342-3805 or [art.ewald@mclaren.org](mailto:art.ewald@mclaren.org).

Sincerely,

A handwritten signature in black ink, appearing to read "Chris J. Conlin".

Christopher J. Conlin, M.D.  
Radiation Safety Officer

A handwritten signature in black ink, appearing to read "Brent Wheeler".

Brent Wheeler  
VP Ancillary/Support Service

# FedEx

## Express

RT 493

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earthsmart

FedEx carbon-neutral  
envelope shipping

ORIGIN ID: FNTA (810) 342-2263  
SHIPPING DEPARTMENT  
MCLAREN  
401 S. BALLENGER HWY

FLINT, MI 485323685  
UNITED STATES US

SHIP DATE: 08JAN13  
ACTWGT: 1.0 LB MAN  
CAD: 779540/CAFE2453

BILL SENDER

TO MATERIALS LICENSING SECTION  
U.S. NUCLEAR REGULATORY COMMISSION  
2443 WARRENVILLE ROAD  
REGION III  
LISLE IL 60532

DEPT: RADIOLOGY

ALL INFORMATION CONTAINED HEREIN IS UNCLASSIFIED EXCEPT WHERE SHOWN OTHERWISE



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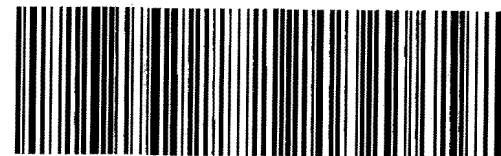
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