



Harper University Hospital
Detroit Medical Center/Wayne State University

Your name here

3990 John R Rd.
Detroit, MI 48201

September 21, 2004

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

Re: Amendment to 21-04127-02

Dear Madam or Sir:

We wish to add the following radionuclide for human use as an agent for both diagnostic imaging and radiopharmaceutical therapy.

<u>Byproduct Material</u>	<u>Form or Manf / Model #</u>	<u>Max. Quantity</u>	<u>Purpose of Use</u>
Holmium-166	Liquid / DOTMP	2 Ci	Diagnostic Imaging & Radiopharmaceutical Therapy of Primary Refractory Multiple Myeloma

This radiopharmaceutical will be supplied as a unit dosage for both diagnostic imaging and therapeutic administration under a company sponsored IND #56915 issued to NeoRx Corporation.

The Radiation Safety Committee (RSC) has reviewed and approved an application for the investigational use of Holmium-166 DOTMP at it's meeting on 9/14/04. Additionally the authorized physician user for this investigation will be Richard N. Joyrich, M.D., RSO and Nuclear Medicine Section Chief as approved by the RSC. This matter has now been forwarded to the Institutional Review Board (IRB) for review and approval. We confirm that an informed consent will be reviewed with and obtained from each human research subject.

www.dmc.org

OCT 12, 2004

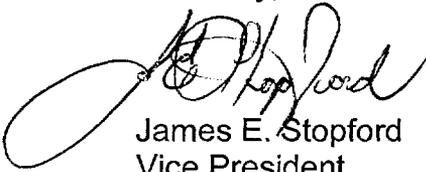
We confirm that the ALARA principle and good radiation safety practice will be maintained at all times and that human research subjects will be released under the conditions specified in 10 CFR 35.75 as required.

The therapeutic portion of this investigation will be conducted under our established "Written Directive" program as required.

It is our intent to refer to the radiopharmaceutical dosage as documented by the supplier licensed under 10 CFR 32.72. Rather than use our ion chamber based dose calibrator due to the limited gamma emissions and high beta emissions of this radiopharmaceutical and the inaccuracies they would cause.

If you have any additional questions concerning this matter, please contact our Medical Nuclear Physicist, Thomas M. Kumpuris, M.S., DABR of Medical Physics Consultants, Inc. 800.321.2207 and fax 313.662.9224.

Sincerely,

A handwritten signature in cursive script, appearing to read "J. Stopford", is written over the typed name and title.

James E. Stopford
Vice President

or a package fee may be applied.



HP 03

Insert A

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William H. ...
Sept 11 ...
1756 ... IL 60534
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Bill to:

Receiver 3rdParty

Paid in Advance

AIRBORNE EXPRESS

1-800-247-2676

10:30 EXP
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Billing Reference (will appear on invoice)

# of Pkgs	Weight (LBS)	Packaging One box must be checked		
		Letter Express <input type="checkbox"/>	Express Pack <input type="checkbox"/>	Other Packaging <input type="checkbox"/>

NAS
(Letter - 5 lbs)

Special Instructions

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(Letter - 150 lbs)

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766 503 4123



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