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Regional Administrator  
Nuclear Materials Safety Branch 2  
Division of Nuclear Materials Safety  
U.S. Nuclear Regulatory Commission, Region 1  
475 Allendale Road  
King of Prussia, PA 19406-1415

November 19, 2008

03034047

RE: Amendment License Number 06-30271-01

Dear Sir or Madam,

We wish to amend our license to appoint Michael Belcourt as the Vion RSO, replacing Greg Laskowski, the current RSO. I have enclosed a summary of Dr. Belcourt's experience and training with radioactive materials.

Please feel free to contact me at (203) 498-4210 or via email ([iking@vionpharm.com](mailto:iking@vionpharm.com)) with any questions concerning the information contained in this request for amendment.

Sincerely,

Ivan King, Ph.D.  
Vice President, Research and Development  
Vion Pharmaceuticals, Inc.  
4 Science Park  
New Haven, CT 06511

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REGION 1  
NOV 21 AM 10:18

Enclosures: Copy of NRC License  
Radioactive materials use by Dr. Belcourt

143026

NMSS/RCM MATERIALS 8-002

Michael Belcourt, Ph.D. – Director of Research and Development Project Management,  
Vion Pharmaceuticals, Inc.

#### History of Use of Radioactive Nuclides

- 1984-1990 University of Connecticut Health Center, Department of Molecular Biology and Biochemistry. Ph.D. in Molecular Biology. Thesis: “Translational Frameshifting in Yeast Ty Elements”; experience included the use of nuclides 32-P, 33-P, and 35-S in DNA labeling and DNA and RNA sequencing.
- 1992-1998 Yale University School of Medicine  
Use of nuclides 3-H and 14-C in DNA and protein labeling experiments.
- 1998-2008 Vion Pharmaceuticals, Inc.  
Use of nuclides 3-H, 14-C, 32-P, 33-P, 35-S, 51-Cr, 125-I and 131-I

#### Training History

- 1984-1990 University of Connecticut Health Center, Office of Radiation Safety. Yearly training and testing involved a written test covering a lecture and 50 page manual on principals of radioactivity and safety including: theoretical aspects, radioactive decay, instrumentation and monitoring, biological hazards, radioactive materials storage, shielding, use, disposal and emergency procedures.
- 1992-1998 Yale University School of Medicine, Office of Chemical and Biological Safety. Training involved attendance of a seminar covering all aspects of radioactive decay, instrumentation and monitoring, biological hazards, radioactive materials storage, shielding, use, disposal and emergency procedures.
- 1998-2008 Vion Pharmaceuticals, Inc. Yearly training covering all aspects of radioactive decay, instrumentation and monitoring, biological hazards, radioactive materials storage, shielding, use, disposal and emergency procedures. Shipping of Packages of Class 7 (Radioactive) Material included packaging, marking, labeling, manifests and declarations of class 7 packages for shipment in compliance with U.S. Department of Transportation. In 2002 at the Yale University School of Medicine, Office of Chemical and Biological Safety, received general radiation safety training with special emphasis on safe handling and use of volatile iodine compounds.
- 2009 (pending) Radiation Safety Officer Training (Radiation Safety Associates, Inc.) 40-hour training course to include mathematics and calculations used in measurements of radioactivity, biological effects of radiation, principles and practices of radiation protection, radioactivity measurements, monitoring techniques and instruments.

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MATERIALS LICENSE

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Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

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| <p>Licensee</p> <p>1. Vion Pharmaceuticals, Inc.</p> <p>2. Four Science Park<br/>New Haven, Connecticut 06511</p> | <p>In accordance with the letter dated December 19, 2007,</p> <p>3. License number 06-30271-01 is amended in its entirety to read as follows:</p> <hr/> <p>4. Expiration date July 31, 2011</p> <hr/> <p>5. Docket No. 030-34047<br/>Reference No.</p> |
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| <p>6. Byproduct, source, and/or special nuclear material</p> <p>A. Hydrogen 3</p> <p>B. Carbon 14</p> <p>C. Phosphorus 32</p> <p>D. Phosphorus 33</p> <p>E. Sulfur 35</p> <p>F. Chromium 51</p> <p>G. Iodine 125</p> <p>H. Iodine 131</p> | <p>Chemical and/or physical form</p> <p>A. Any</p> <p>B. Any</p> <p>C. Any</p> <p>D. Any</p> <p>E. Any</p> <p>F. Any</p> <p>G. Any</p> <p>H. Any</p> | <p>8. Maximum amount that licensee may possess at any one time under this license</p> <p>A. 50 millicuries</p> <p>B. 50 millicuries</p> <p>C. 20 millicuries</p> <p>D. 20 millicuries</p> <p>E. 20 millicuries</p> <p>F. 25 millicuries</p> <p>G. 5 millicuries</p> <p>H. 5 millicuries</p> |
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9. Authorized use:

A. Through H. Research and development as defined in 10 CFR 30.4; animal studies.

CONDITIONS

10. Licensed material may be used or stored only at the licensee's facilities located at Four Science Park, New Haven, Connecticut.

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**MATERIALS LICENSE  
SUPPLEMENTARY SHEET**

Duplicate

License Number

06-30271-01

Duplicate

Docket or Reference Number

030-34047

Amendment No. 5

11. Licensed material shall be used by, or under the supervision of, Michael Belcourt, Ph.D. and Greg Laskowski. Licensed material listed in Items 6.A and 6.B. also shall be used by, or under the supervision of, Ala Nassar, Ph.D.
12. The Radiation Safety Officer for this license is Greg Laskowski.
13. The licensee shall not use licensed material in or on human beings.
14. The licensee shall not use licensed material in field applications where it is released except as provided otherwise by specific condition of this license.
15. Experimental animals, or the products from experimental animals, that have been administered licensed materials shall not be used for human consumption.
16. The licensee is authorized to hold byproduct material with a physical half-life of less than 120 days for decay-in-storage before disposal without regard to its radioactivity if it:
  - A. Monitors byproduct material at the surface before disposal and determines that its radioactivity cannot be distinguished from the background radiation level with an appropriate radiation detection survey meter set on its most sensitive scale and with no interposed shielding; and
  - B. Removes or obliterates all radiation labels, except for radiation labels on materials that are within containers and that will be managed as biomedical waste after they have been released from the licensee; and
  - C. Maintains records of the disposal of licensed materials for 3 years. The record must include the date of disposal, the survey instrument used, the background radiation level, the radiation level measured at the surface of each waste container, and the name of the individual who performed the disposal.
17. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

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18. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. The U.S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.

A. Application dated July 13, 2001 [ML012040156]



For the U.S. Nuclear Regulatory Commission

Date March 21, 2008

By Original signed by Dennis R. Lawyer

Dennis R. Lawyer  
Commercial and R&D Branch  
Division of Nuclear Materials Safety  
Region I  
King of Prussia, Pennsylvania 19406

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

11/19/2008, and to inform you that the initial processing which includes an administrative review has been performed.

*AMERIS. 06-30271-01* 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** 143026.  
When calling to inquire about this action, please refer to this control number.  
You may call us on (610) 337-5398, or 337-5260.