PHARMA-LOGIC
THE LOGICAL CHOICE

June 25, 2008

Loren Hueter
United States Nuclear Regulatory Commission
2443 Warrenville Road Suite 210
Lisle, IL 60532-4352

Re: License Number 21-32190-01MD

Mr. Hueter:

This letter is a request to have the following authorize user, James M. Bichler, added to our pharmacy's NRC license.

His current address is 417 Comfort Lane Traverse City, MI 49686

Jim received his authorized user training from Ohio State University in October 2002. He was previously employed by Mallinkrodt, Inc. in the state of Ohio and was listed as an Authorized Nuclear Pharmacist on their license number 02500310002. Jim began employment with PharmaLogic MI on June 16, 2008 and is in the process of reciprocating his pharmacy license to Michigan.
His Ohio pharmacist license number is 03-3-25579. He also holds pharmacist licenses in Colorado (PHA-17029) and Wisconsin (13800-40).

Enclosed is his authorized user training documentation, a copy of the RAM license in which he was named an authorized user from the state of Ohio, and copies of his pharmacists licenses from Ohio, Colorado, and Wisconsin.

Please call or e-mail me with any question or requests for further information. The pharmacy contact number is 231-929-7200 and my e-mail address is dana.suttle@gmail.com

If a copy of the amendment could be faxed to me at 231-929-4457 upon its completion, I would be most appreciative.

Sincerely,

Dana Suttle, R.Ph
Pharmacy Manager
PharrmaLogic MI

RECEIVED JUL 0 7 2008

Pharmalogic MI, L.L.C. • 1144 Boon Street • Traverse City, MI 49686
231-929-7200 • Fax 231-929-4457

TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

Name: James M. Bichler, Pharm.D.

Location of Training	Date(s) of Attendance	Course Title	Total Clock Hours of Course	BREAKDOWN OF COURSE CONTENT IN CLOCK HOURS				
				Radiation Physics & Instrumentation	Radiation Protection	Math Pertaining to Radioactivity	Radiation Biology	Radiopharmaceutical Chemistry
The Ohio State University, Columbus, OH	September 23, 2002 through October 25, 2002	Nuclear Pharmacy Certificate Program	214	88	45	20	22	39
*Note: Show a breakdown of hours by institution, dates, and subjects. List each hour only once (i.e., under the most applicable subject category) TOTAL HOURS			214	88	45	20	22	39

Authorized Nuclear Pharmacist/Authorized User: George H. Hinkle
George H. Hinkle, RPh,MS,BCNP,FASHP,FAPhA

DATE: October 25, 2002

Amendment 9

OHIO DEPARTMENT OF HEALTH
LICENSE FOR RADIOACTIVE MATERIAL

Pursuant to Chapter 3748 of the Ohio Revised Code, and in reliance on statements and representations made by the licensee, a license is hereby issued authorizing the licensee named herein to receive, acquire, possess, and transfer radioactive material as 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 applications of Chapter 3748 of the Ohio Revised Code and all applicable rule promulgated thereunder. This license is subject to all applicable rules, regulations and orders of the Ohio Department of Health now or hereinafter in effect and to any condition specified below.

LICENSEE	LICENSE NUMBER
1. Mallinckrodt, Inc.	3. 02500310002
2. 675 McDonnell Boulevard P.O. Box 5840 St. Louis, Missouri 63134	EXPIRATION DATE 4. February 1, 2007
	BUREAU DOCKET NUMBER 5. DC-09-12-01

6. RADIOACTIVE MATERIAL	7. CHEMICAL AND/OR PHYSICAL FORM	8. MAXIMUM QUANTITY THAT LICENSEE MAY POSSESS AT ANY ONE TIME UNDER THIS LICENSE
A. Any radioactive material identified in 10 CFR 35.100	A. Any radiopharmaceutical form	A. 3.7 GBq (100 mCi) total
B. Any radioactive material identified in 10 CFR 35.200, except Technetium-99m, Iodine-131, Thallium-201, and Xenon-133	B. Any radiopharmaceutical form	B. 18.5 GBq (500 mCi) total
C. Any radioactive material identified in 10 CFR 35.300, except Iodine-131 and Ytterium-90	C. Any radiopharmaceutical form	C. 18.5 GBq (500 mCi) total
D. Xenon-133	D. Unit dose containers of gas or gas in solution.	D. 148 GBq (4.0 Ci)
E. Thallium-201	E. Thallous Chloride	E. 92.5 GBq (2.5 Ci)
F. Iodine-131	F. Any radiopharmaceutical form	F. 37 GBq (1.0 Ci)
G. Ytrrium-90	G. Any form	G. 37 GBq (1.0 Ci)
H. Technetium-99m	H. Any radiopharmaceutical form	H. 7.4 TBq (200 Ci)
I. Molybdenum-99	I. Any molybdenum-99 / technetium-99m generator initially distributed in accordance with a specific license issued pursuant to rule 3701:1-46-43 or a specific license issued to a manufacturer by the USNRC or an Agreement State pursuant to equivalent state regulations.	I. 7.4 TBq (200 Ci)

OHIO DEPARTMENT OF HEALTH LICENSE FOR RADIOACTIVE MATERIALS SUPPLEMENTARY SHEET	License Number: 02500310002 Bureau Docket Number: DC09-12-01 Amendment No. 9

E. The leak test shall be capable of detecting the presence of 185 Bq (0.005μCi) of radioactive material on the test sample. If the test reveals the presence of 185 Bq (0.005 μCi) or more of removable contamination, a report shall be filed with the Ohio Department of Health, and the source shall be removed immediately from service and decontaminated, repaired, or disposed of in accordance with Ohio Depart of Health regulations. The report shall be filed within 5 days of the date of the leak tests result is known with the Bureau of Radiation Protection – Ohio Department of Health, 246 North High Street, P.O. Box 118, Columbus, Ohio 43266-0118. The report shall specify the source involved, the test results, and corrective action taken.

F. The licensee is authorized to collect leak test samples for analysis. Alternatively, tests for leakage and/or contamination may be performed by persons specifically licensed by the Director, the NRC or an Agreement or NARM licensing state to perform such services.

G. All sealed sources that are used or obtained shall have been evaluated and approved under the provisions of rule 3701:1-46-49 of the Ohio Administrative Code or by equivalent NRC, Agreement State, or NARM licensing state regulation.

20. The license is authorized to hold radioactive material with a physical half life of less than 120 days for decay in storage before disposal in ordinary trash, provided:

A. Waste to be disposed of in the manner shall be held for decay a minimum of ten half-lives.

B. Before disposal as ordinary trash, the waste shall be surveyed at the container surface with the appropriate survey instrument set o its most sensitive scale with no interposed shielding to determine that its radioactivity cannot be distinguished from background. All radiation labels shall be removed or obliterated.

C. A record of each disposal shall be retained for three years. The record must include the date of the disposal, the date on which the product was placed in storage, the radionuclides disposed of, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name of the individual who performed the survey.

21. Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders by the licensee.

22. Notwithstanding the requirements of rule 3701:1-46-43(C) of the Ohio Administrative Code, the licensee may re-distribute alpha, beta, or photon-emitting radioactive drugs, which have been initially distributed by another radiopharmaceutical supplier licensed pursuant to rule 3701:1-46-43 of the Ohio Administrative Code, without verifying the radioactivity of the dosage. The licensee must not manipulate the dosage, including the packaging and the label.

23. In addition to the possession limits in item 8, the licensee shall further restrict the possession of sealed sources licensed material to quantities below the minimum limit specified in rule 3701:1-40-17(C) of the Ohio Administrative Code, for establishing decommissioning financial assurance.

24. 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 Ohio Department of Health's statutes, rules, and orders shall govern unless statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.

A. Application dated December 7, 2001 and letters dated January 14 and January 25, 2002.
B. Letters dated July 16, and July 23, 2002 (Amendment 1).
C. Letter dated September 5, 2002 (Amendment 2).
D. Letter dated January 17, 2003 (Amendment 3).
E. Letter dated September 11, 2003 (Amendment 4).
F. Letter dated October 10, 2003 (Amendment 5)
G. Letter dated December 26, 2003 (Amendment 6)
H. Letter dated April 05, 2004 (Amendment 7)
I. Letter dated September 20, 2004 (Amendment 8)
J. *Letter dated March 10, 2005 (Amendment 9)*

FOR THE OHIO DEPARTMENT OF HEALTH

Date: 4/14/05

By: _____
Director, Ohio Department of Health

OHIO DEPARTMENT OF HEALTH LICENSE FOR RADIOACTIVE MATERIALS SUPPLEMENTARY SHEET	Page 3 of 4 License Number: 02500310002 Bureau Docket Number: DC09-12-01 Amendment No. 9

12. Licensed material shall be limited by the procedures outlined in Sections 6, 7, and 8 of this license. Materials may only be used by, or under the supervision of, the below listed individual(s) designated in writing:

Authorize Nuclear Pharmacists/ Authorized Users:

A. Christine Basilone, R. Ph.
B. James Bichler, R. Ph.
C. Lisa Ann Coats, R. Ph.
D. James M. Dawson, R. Ph.
E. Joseph M. Gatton, R. Ph.
F. David Herrmann, R.Ph.
G. Amanda Kochert, R. Ph.
H. James Korczynski, R. Ph.
I. Lisa L. Kous, R. Ph.
J. David R. Lutes, R. Ph.
K. John Nygard, R. Ph.
L. Bradley M. Roff, R. Ph.
M. Darlene Rubin, R. Ph.
N. Ruth Mary Wetzel, R. Ph.
O. Deidre Rose, R. Ph.

13. Nuclear Pharmacists performing licensed activities shall be licensed by and in good standing with the state of Ohio.

14. Annual refresher Radiation Safety Training shall be conducted at intervals not to exceed 13 months.

15. A formal written program ALARA review by the Radiation Safety Officer shall be conducted at least annually. These reports shall be maintained for review by Ohio Department of Health Inspector(s).

16. The licensee is authorized to transport licensed material in accordance with Chapter 3701:1-50 of the Ohio Administrative Code.

17. The licensee shall conduct a physical inventory every 6 months to account for all sealed sources/and or devices received and possessed under the license. Records of inventories shall be maintained for at least 3 years from the date of each inventory, and shall include: the quantities and the kinds of licensed material; manufacturer's name and model and serial numbers, if available; location of the sources; the date of the inventory, and the signature of the Radiation safety Officer after reviewing the record.

18. Radioiodine solution and capsules containing radioiodine solution will be stored within the glove box with the exception of I-131 Tositummomab (Bexxar®). The licensee will follow operations involving I-131 Bexxar ® as stated in letter dated September 11, 2003.

19. Sealed Sources

A. Sealed sources shall be tested for leakage and/or contamination at intervals not to exceed six (6) months.

B. Notwithstanding paragraph A of this condition, sealed sources designed to emit alpha particles shall be tested for leakage and/or contamination at intervals not exceed three (3) months.

C. In the absence of a certificate from a transferor indicating that a leak test has been made within the required leak test interval, a sealed source shall not be put into service until tested.

D. Sealed sources need not be tested if:

1) They contain only a radioactive gas; or

2) The half-life of the radioisotope is 30 days or less; or

3) They contain 3.7 MBq (100μCi) or less of beta or gamma emitting material or 370 KBq (10μCi) or less of alpha-emitting material; or

4) They are in storage and are not be used. However, when they are removed for use or transfer to another person, and have not been tested within the required leak test interval, they shall be tested before use or transfer. No sealed source shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.

OHIO DEPARTMENT OF HEALTH LICENSE FOR RADIOACTIVE MATERIALS SUPPLEMENTARY SHEET	Page 2 of 4 License Number: 02500310002 Bureau Docket Number: DC09-12-01 Amendment No. 9

6. RADIOACTIVE MATERIAL	7. CHEMICAL AND/OR PHYSICAL FORM	8. MAXIMUM QUANTITY THAT LICENSEE MAY POSSESS AT ANY ONE TIME UNDER THIS LICENSE
J. Any radioactive material authorized under 10 CFR 35.57(a)	J. Any sealed source listed in 10 CFR 35.57(a) that has been manufactured, labeled, packaged, and distributed in accordance with a specific license issued pursuant to rule 3701:1-46-44 or a specific license issued to a manufacturer by the USNRC or an Agreement State pursuant to equivalent state regulations.	J. 11.1 GBq (300 mCi)
K. Any radioactive material listed in rule 3701:1-46-11 of the Ohio Administrative Code	K. Prepackaged units for in vitro diagnostic tests	K. 740 MBq (20 mCi)
L. Radioactive material with atomic numbers between 3 and 83, inclusive	L. Sealed source leak test samples	L. As needed
M. Uranium (depleted Uranium-235)	M. Metal encased in stainless steel	M. 608 kilograms

9. Authorized Use

A - H. Preparation and distribution of radioactive drugs (including Mo-99m/Tc-99m generators) to authorized recipients.

H. and I. Distribution, redistribution and use of generators for the purpose of radiopharmaceutical elution.

J. Instrument calibration. Redistribution of sources to specifically authorized recipients. Pursuant to rule 3701:1-46-44 of the Ohio Administrative Code, the licensee is authorized to redistribute sources to person licensed pursuant to 10 CFR 35.57(a), as delineated in rule 3701-39-02.1 of the Ohio Administrative Code, USNRC, NARM licensing state or under equivalent licenses of Agreement States.

K. Redistribution to specific licenses or general licenses pursuant to rule 3701:1-46-11 of the Ohio Administrative Code provided the packaging and the labeling remain unchanged.

L. In-house analysis of sealed source leak samples.

M. Shielding for Mo-99/Tc-99m generators.

CONDITIONS

10. Licensed material may only be used at the licensee's facilities located at:

4623 Wesley Avenue
Cincinnati, Ohio 45212

11. The Radiation Safety Officer or Person in charge of the radioactive material for this license is: Christine Basilone, R. Ph.

Home

Ohio State Board of Pharmacy

License Search Results

Key: LAST NAME starts with 'BICHLER' and FIRST NAME starts with 'JAMES'

For more information, please click the name.

Name	State	License	First License Issue Date
BICHLER, JAMES	OH	03-3-25579	01/07/2003

This data is an accurate representation of information currently maintained by the Ohio State Board of Pharmacy as of June 16, 2008.

Current JCAHO standards allow the use of a secure internet based system for licensure verification.

This information is otherwise provided as a public service and no user may claim detrimental reliance thereon.

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http://www.state.oh.us/pharmacy/query/query.asp
This page updated April 5, 2001

State of Wisconsin Department of Regulation & Licensing
Online Applications: License Lookup

Wisconsin License Lookup

Credential Summary.

Credential Summary for 13800-40

Name:	BICHLER, JAMES
Credential Type:	Pharmacist (40)
Credential Number:	13800-40
Location:	RANDOM LAKE, WI
License Type:	regular
Status	credential license is current (active)
Eligible To Practice:	YES
First Fee Received:	05/07/2008

Details Requirements Payments Orders Relationships

Credential Detail

License current through:	2010-05-31
Granted date:	2002-10-10
Multi-state:	N/A
Orders:	NONE
Specialties:	
Other Names:	James M Bichler

Consistent with JCAHO and NCQA standards for primary source verification.
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Questions?
Send an e-mail, or call (608) 266-2112 between 7:45 a.m. and 2:00 p.m., Central Time.

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James Michael Bichler

Address	Random Lake , WI 53075
License Number	PHA-17029
License Type	Pharmacist
License Status	Active
License Method	License Transfer
License First Issued	April 22, 2005
Last Renewal Date	November 01, 2007
Last Expiration Date	October 31, 2009
Board or Program Actions	No actions on file (Information about Program or Board Actions)

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Loren Heuter
US Nuclear Regulatory Commission
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