

MATERIALS LICENSE

Amendment No. 45

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.

302456

Licensee

1. Merrill Pharmaceuticals, Inc.

2. 2110 E. Galbraith Road
Cincinnati, OH 45215In accordance with letter dated
March 24, 19973. License Number 34-03643-01 is amended in
its entirety to read as follows:

4. Expiration Date November 30, 2001

5. Docket or
Reference No. 030-056966. Byproduct, Source, and/or
Special Nuclear Material7. Chemical and/or Physical
Form8. Maximum Amount that Licensee
May Possess at Any One Time
Under This License

A. Carbon-14

A. Any

A. 5 curies

B. Hydrogen-3

B. Any

B. 5 curies

C. Phosphorus-32

C. Any

C. 100 millicuries

D. Sulfur-35

D. Any

D. 200 millicuries

E. Iodine-131

E. Any

E. 100 millicuries

F. Iodine-125

F. Any

F. 75 millicuries

G. Iron-59

G. Any

G. 25 millicuries

H. Iron-55

H. Any

H. 50 millicuries

I. Calcium-45

I. Any

I. 50 millicuries

J. Cerium-141

J. Any

J. 25 millicuries

K. Strontium-85

K. Any

K. 25 millicuries

L. Chromium-51

L. Any

L. 50 millicuries

M. Nickel-63

M. Foil source (contained
in Hewlett Packard
Detector Cell Model
19282)M. One cell not to
exceed 15 millicuries

110087

9704140028 970404
PDR ADOCK 03005696
C PDR

COPY

ML
230
CD

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number

34-03643-01

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6. Byproduct, source,
and/or special nuclear
material

7. Chemical and/or
physical form

8. Maximum amount that
licensee may possess
at any one time
under this license

N. Rubidium-86

N. Any

N. 25 millicuries

O. Yttrium-90

O. Any

O. 50 millicuries

P. Technetium-99m

P. Any

P. 500 millicuries

Q. Chlorine-36

Q. Any

Q. 50 millicuries

R. Nickel-63

R. Any

R. 10 millicuries

S. Phosphorus-33

S. Any

S. 100 millicuries

T. Potassium-42

T. Any

T. 50 millicuries

U. Cesium-137

U. Sealed source(s)
(J. L. Shepherd
and Associates
Model 6810)

U. 2,400 curies

V. Cesium-137

V. Sealed source(s)
(registered pursuant
to Section 32.210 of
10 CFR Part 32 or an
Agreement State)

V. No single source
to exceed 100
microcuries

9. Authorized Use:

A. through L., O. through T. To be used for in vitro studies and tracer studies in small animals as described in application dated February 14, 1991 and letter (with attachments) received October 22, 1991.

M. For use in a gas chromatograph for sample analysis.

N. To be used for in vitro studies.

U. To be used in a J.L. Shepherd and Associates Mark I irradiator for irradiation of biological materials (excluding explosive and highly flammable products).

V. To be used as instrument/alarm check sources.

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CONDITIONS

10. Licensed material shall be used only at the licensee's facilities located at 2110 East Galbraith Road, Cincinnati, Ohio.
11. Licensed material shall be used by, or under the supervision of, individuals who have been trained in accordance with Item 10. of application dated February 14, 1991, letter received October 22, 1991, and letter dated December 11, 1992.
12. The Radiation Protection Officer for the activities authorized by this license is Cort Horton.
13. Licensed material shall not be used in or on human beings or in field applications where activity is released except as provided otherwise by specific condition of this license.
14. Experimental animals administered licensed materials or their products shall not be used for human consumption.
15. A. (1) Each sealed source containing licensed material, other than Hydrogen-3, with a half-life greater than thirty days and in any form other than gas shall be tested for leakage and/or contamination at intervals not to exceed six months; except those sealed sources as specified by the manufacturer and specifically authorized by the Commission or an Agreement State may be leak tested at intervals not to exceed three years. In the absence of a certificate from a transferor indicating that a test has been made within six months prior to the transfer, a sealed source received from another person shall not be put into use until tested.
(2) Notwithstanding the periodic leak test required by this condition, any licensed sealed source is exempt from such leak test when the source contains 100 microcuries or less of beta and/or gamma emitting material or 10 microcuries or less of alpha emitting material.
- B. Any source in storage and not being used need not be tested. When the source is removed from storage for use or transfer to another person, it shall be tested before use or transfer.

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- C. The test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. If the test reveals the presence of 0.005 microcurie or more of removable contamination, the source shall be removed from service and decontaminated, repaired, or disposed of in accordance with Commission regulations. A report shall be filed within 5 days of the date the leak test result is known with the U.S. Nuclear Regulatory Commission, Region III, 801 Warrenville Road, Lisle, Illinois 60532-4351, ATTN: Chief, Nuclear Materials Safety Branch. The report shall specify the source involved, the test results, and corrective action taken. Records of leak test results shall be kept in units of microcuries and shall be maintained for inspection by the Commission. Records may be disposed of following Commission inspection.
- D. Tests for leakage and/or contamination shall be performed by the licensee or by other persons specifically licensed by the Commission or an Agreement State to perform such services.
16. In lieu of using the conventional radiation caution colors (magenta or purple on yellow background) as provided in Section 20.203(a)(1), of 10 CFR Part 20, the licensee is hereby authorized to label detector cells and cell baths, containing licensed material and used in gas chromatography devices, with conspicuously etched or stamped radiation caution symbols without a color requirement.
17. Maintenance, repair, cleaning, replacement, and disposal of foils contained in detector cells shall be performed only by the device manufacturer or other persons specifically authorized by the Commission or an Agreement State to perform such services.
18. Detector cells containing licensed material shall not be opened or the sources removed from the detector cell by the licensee.
19. The licensee shall conduct a physical inventory every six (6) months to account for all sealed sources received and possessed under the license. The records of the inventories shall be maintained for two (2) years from the date of the inventory for inspection by the Commission, and shall include the quantities and kinds of byproduct material, manufacturer's name and model numbers, location of sealed sources and the date of the inventory.
20. The licensee is authorized to hold radioactive material with a physical half-life of less than 65 days for decay-in-storage before disposal in ordinary trash provided:
- A. Radioactive waste to be disposed of in this manner shall be held for decay a minimum of 10 half-lives.
- B. Before disposal as normal waste, radioactive waste shall be surveyed to determine that its radioactivity cannot be distinguished from background. All radiation labels shall be removed or obliterated.

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21. The licensee shall not perform repairs or alterations of the irradiator involving removal of shielding or access to the licensed material. Removal, replacement, and disposal of sealed sources in the irradiator shall be performed by a person specifically licensed by the Commission or an Agreement State to perform such services.
22. For each J. L. Shepherd and Associates, Mark I Cesium-137 Irradiator installed and used, the licensee shall:
- A. Permit the use of the irradiator only when a calibrated and operable radiation survey meter or room monitor is available; and
 - B. Permit the irradiator door to be opened only after the operator has checked visual indicators to verify that the source has returned to its safe storage position; and
 - C. Have room monitors installed that will:
 - (i) Operate at all times when the irradiator is in use; and
 - (ii) Activate a visible and audible alarm when radiation exceeds 2 millirems per hour; and
 - (iii) Detect any radiation leaking from the irradiator door; and
 - (iv) Be visible to the irradiator user when he is next to the irradiator; or
 - D. If a room monitor is not installed, have available a calibrated and operable survey meter which will be used to:
 - (i) Determine the radiation level at the irradiation door when the door is closed; and
 - (ii) Check for any increase in radiation levels each time the irradiator door is opened.
 - E. Immediately stop the use of the irradiator and notify the U.S. Nuclear Regulatory Commission, Region III, 801 Warrenville Road, Lisle, Illinois 60532-4351, ATTN: Chief, Nuclear Materials Safety Branch, by telephone if abnormal levels of radiation or any malfunction of the irradiator is detected; and
 - F. Not repair or authorize repairs of the irradiator except by the manufacturer or other persons specifically authorized by the Commission or an Agreement State to perform such services.

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23. The procedures attached to letter dated March 15, 1993, shall be followed and a copy of these instructions shall be made available to each individual using or having responsibility for use of licensed material. Any changes in these instructions shall have the prior approval of the Material Licensing Section, Region III, U.S. Nuclear Regulatory Commission, 801 Warrenville Road, Lisle, IL 60532-4351.
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 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 February 14, 1991;
 - B. Letter received October 22, 1991 (with attachments); and
 - C. Letters dated June 1, 1992, December 11, 1992, March 15, 1993 (with attached procedures), September 2, 1993, October 29, 1993 and July 14, 1995.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date

4/4/97

By

Kevin G. Hall

Nuclear Materials Licensing Branch, Region III

(FOR LFMS USE)
INFORMATION FROM LTS

R2

BETWEEN:

License Fee Management Branch, ARM
and
Regional Licensing Sections

Program Code: 03611
Status Code: 0
Fee Category: 3M 3E
Exp. Date: 20030731
Fee Comments:
Decon Fin Assur Req'd: Y

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED

Applicant/Licensee: MERRILL PHARMACEUTICALS, INC.
Received Date: 970325
Docket No: 3005696
Control No.: 302456
License No.: 34-03643-01
Action Type: Amendment

2. FEE ATTACHED

Amount: 610.00
Check No.: 1303784

3. COMMENTS

Signed _____
Date 3/27/97

B. LICENSE FEE MANAGEMENT BRANCH (Check when milestone 03 is entered / /)

1. Fee Category and Amount: 3M 3E \$610

2. Correct Fee Paid. Application may be processed for:

Amendment _____
Renewal _____
License _____

3. OTHER

Signed SC
Date 4/1/97

APR 03 1997

Log	MAR 12 III
Remitter	
Check No.	1303784
Amount	\$610
Fee Category	3M 3E
Type of Fee	And
Date Check Rec'd	3/31/97
Date Completed	4/1/97
By:	SC

1997 MAR 31 PM 4:22

March 24, 1997

Hoechst Marion Roussel, Inc.

Mail: P.O. Box 156300
2110 East Galbraith Road
Cincinnati, OH 45215-6300
Telephone (513) 948-9111
Fax (513) 948-7076

Mr. Kevin Null, Senior Licensing Reviewer
United States Nuclear Regulatory Commission
Region III, Material Licensing Section
801 Warrenville Road
Lisle, IL 60532-1351

Subject: Request for Radiation Safety Officer (RSO) Name Change
for Material License Number 34-03643-01

Dear Mr. Null:

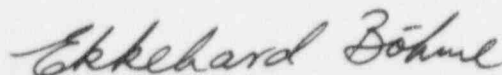
Merrell Pharmaceuticals, Inc., requests an amendment to the above referenced material license to change the named RSO from Phillip J. Lachmann to Cort N. Horton. Mr. Horton will replace Mr. Lachmann as the RSO when the NRC approves this request. Mr. Lachmann has accepted another position within the Company.

Mr. Horton has considerable work experience in operational health physics and working with the Nuclear Regulatory Commission (NRC). Mr. Horton is currently the Assistant RSO for Hoechst Marion Roussel, providing technical support to the radiation safety program. Mr. Horton is employed by Bartlett Nuclear Services who is contracted to provide technical support to Hoechst Marion Roussel, Inc. Mr. Horton holds a Bachelor of Science degree in Health Physics and a Masters of Science degree in Environmental Management. Mr. Horton's qualifications and experience are presented in the enclosed resume for your review.

Also enclosed with this transmittal is check number 1303784 in the amount of six hundred and ten dollars (\$610.00) to cover the cost of the requested amendment.

Please contact me at 513/948-7003 or Cort Horton at 513/948-7554 if you need additional information. Your timely consideration for this request will be appreciated.

Sincerely,



Ekkehard H.W. Böhme, Ph.D.
Manager, Technical & Facilities Services

EHWB/jfs

RECEIVED

MAR 25 1997

REGION 1.1

Hoechst Marion Roussel
A member of the Hoechst Group

Hoechst 

MAR 25 1997

302456

PM: 3-24-97

Cort Newlyn Horton
9243 Deercross Parkway
Blue Ash, Ohio 45236
513/793-4592

Education

M.S. Environmental Management, Findlay University, Findlay, Ohio (Dec. 1996)
B.S. Radiation and Nuclear Engineering, Oklahoma State University (1977)
40-Hour Mine Safety Training, WIPP
40-Hour Radiation Worker Training
In Place Filter Testing - Harvard School of Public Health
Advanced Hazardous Material Transportation
Advanced Hazardous Waste Transportation

Experience

February 1997 to Present
Bartlett Nuclear Services
Assistant Radiation Safety Officer

Provide technical and administrative support for Hoechst Marion Roussel, Inc. radiation safety programs as required by 10CFR parts 20 and 30. Activities for the Nuclear Regulatory Commission (NRC) licensee included maintenance support for personnel dosimetry, radiological surveys for contamination control, radiation safety training for pharmacology research personnel and maintenance of data bases for radioisotope inventory and waste management. Provides supervision for health physics technicians and support for emergency response to radiological and chemical incidents. Provides notification to the NRC as required by the material license, and Federal and State regulations.

Provided NRC material License maintenance including applications for amendments as required by 10CRF30. Maintained radiation safety program records system and provided support for internal and external program audits. Provided other company RSO's technical support for programs endorsed by agreement and nonagreement states.

February 1992 to October 1996
Battelle Memorial Institute
Field Services Department Manager

Responsible for Analytical Laboratory, Waste Management and Characterization activities in support of the Battelle Columbus Laboratories Decommissioning Project (BCLDP). The BCLDP is a partnership between Battelle Memorial Institute and the Department of Energy to decontaminate 15 privately owned buildings by Battelle in Columbus, Ohio. The Field Services Manager provides technical and administrative support for professional and technical staff; 62 technical personnel are charged with packaging and transporting hazardous material for disposal, assessing levels of radiological and chemical contaminants prior to decontamination, and providing analytical service through an on-site laboratory and off-site contracts. The department is supported by an \$8.5M annual budget, which includes waste disposal, professional subcontracts, and technical support services.

- Acquired an *exemption to DOE orders* to allow waste disposal at a private sector facility
- Establishing and maintaining exceptional performance in the DOE Analytical Laboratory Intercomparison Program.
- Implemented new business development program to provide D&D consulting services to DOE and private sector clients. Present *commitments exceed \$1.4M* from outside

Experience

Mr. Horton has 18 years' experience in operational health physics and waste management. This experience includes management and technical application. He has managed the decommissioning of a radium dial facility and was the project manager for the collection of over 2,000 radioactive samples. Mr. Horton also managed the successful decontamination of several floating barges for a major oil company and the Department of Energy (DOE).

Mr. Horton has served as project manager for the decommissioning of a radioactive source manufacturing facility which operated under Nuclear Regulatory Requirements; provided health physics support for DOE and DoD operating facilities, as well as private sector; and provided technical support to Lawrence Livermore Labs, Pantex, and Weldon Springs.

Mr. Horton's extensive experience at DOE facilities includes National Environmental Policy Act (NEPA) documentation for a new ventilation shaft at the Waste Isolation Pilot Plant (WIPP); shielding analysis for the Transuranic Package Transporter (TRUPACT); writing environmental monitoring reports using computer models; and performing audits for transuranic waste certification at Savannah River, Oak Ridge, and Lawrence Livermore Laboratory. Mr. Horton also implemented the passive/active neutron interrogation instrumentation that was developed by Los Alamos Scientific Laboratory for use by the DOE TRU waste generators.

The experience that Mr. Horton offers is a combination of Government and private sector. His interaction with many DOE facilities and defense entities is coupled with services provided for major oil companies and chemical manufacturers.

September 1988 - February 1992

Jacobs Engineering Company, St. Charles, Missouri
Senior Health Physicist

Provided general engineering and health physics support during decontamination and decommissioning of a DOE uranium process facility. Developed subcontracts for hydrolyzing, abrasive blasting, and acid washes. Assisted with contract negotiations within the DOE procurement system. Developed implementation plans for DOE orders. Developed packaging and shipping requirements for hazardous materials in accordance with 49CFR requirements.

Responsible for implementing radiation protection controls during the remediation of the Weldon Spring site near St. Louis, Missouri. Established the implementation of DOE Order 5480.11,

Radiation Protection. Facilitated the building of an RCRA storage area for hazardous waste. Performed and supervised all hazardous material shipments including radioactive, explosive, poison, and flammable DOT hazard classes.

August 1987 - September 1988

Westinghouse Electric Company, Carlsbad, New Mexico

Senior Engineer

Developed the radiation protection program for the Waste Isolation Pilot Plant (WIPP) outside of Carlsbad, New Mexico. Performed shielding analysis for the Transuranic Package Transporter (TRUPACII). Developed NEPA documentation for the new ventilation shaft prior to the WIPP's receiving TRU waste. Member of the TRU Waste Certification Committee to certify generators to ship TRU waste to the WIPP for disposal. Developed the technical contract for the implementation of the mobile NDA/NDE equipment designed by Los Alamos Scientific Laboratory.

December 1984 - February 1987

IT Corporation, Knoxville, Tennessee

Project Manager/Sr. Health Physics Supervisor

Supported a variety of decontamination and decommissioning projects. Developed and implemented radiation protection programs, performed cost tracking, hiring and development of project staff, and extensive client interaction. Also managed smaller projects. Maintained and operated field laboratory performing gamma spectroscopy, liquid scintillation, and proportional counting.

December 1983 - December 1984

Mare Island Naval Shipyard, Valljo, California

Health Physicist

Performed environmental monitoring and radiological accident investigation in support of nuclear submarine refueling. Member of Radiological Response Team. Coordinated radiation dosimetry program for several thousand workers supporting three shifts.

March 1980 - November 1982

Dowell Division of Dow Chemical, Houston, Texas

District Engineer

Responsible for design and implementation of cementing and stimulation treatments for oil/gas well servicing (deep/ultra deep). Provided technical training and on-location assistance for service engineers. Interacted with customers concerning applications of petroleum completion fluids, squeeze cementing techniques, and plugs. Responsibilities also included sales support, quality assurance, and development of engineering trainees. **District Radiation Safety Officer** provided for shipping radioactive sources, application of tracers and nails, and personnel radiation monitoring.

October 1978 - March 1980

**Oklahoma State Department of Health, Oklahoma City, Oklahoma
Health Physicist**

Performed monitoring, procedure development, and instrument calibration in support of environmental monitoring program. Established initial emergency response program for the proposed Blackfox Nuclear Power Reactor. Maintained dosimetry and radiation protection training records.

June 1977 - October 1978

**Mason and Hanger Co., Amarillo, Texas
Health Physicist**

Provided health physics support to nuclear weapons manufacturing effort. Ensured that radiography complied with NIST standards and that operating procedures were maintained. Completed dose evaluations and made shielding recommendations for personnel protection. Developed and presented training courses for radiation safety and nuclear criticality safety. Type "Q" National Defense Security Clearance, June 1977.

Publications

1977 - Environmental Monitoring Report, Mason and Hanger Co., Inc., Pantex Plant, Amarillo, Texas

1981 - Radiation Safety Manual; Dowell Division of Dow Chemical

Appointments

Member Residual Radioactivity and Recycling Workshop--U.S. Environmental Protection Agency and Japanese Atomic Energy Research Institute, Invited Speaker, Mito, Japan, 1994.

Pollution Prevention Conference--1994 Honorable Mention

Decommissioning Televideo Program--1995 Presenter

APR 07 1997

Ekkehard H. W. Bohme, Ph.D.
Manager, Technical & Facilities Services
Merrell Pharmaceuticals, Inc.
2110 East Galbraith Road
Cincinnati, OH 45215-6300

Dear Dr. Bohme:

Enclosed is the NRC license amendment which you requested.

Also note that your license expiration date has been extended to November 30, 2001. This was done in accordance with NRC letter dated May 7, 1996, from Donald Cool to Phillip Lachmann.

You are encouraged to carefully review your license amendment upon receipt as special conditions may have been added to ensure that the changes requested meet NRC requirements.

Any future correspondence relating to your license should specifically reference your license number to expedite your inquiry.

Should you have any questions regarding your new license amendment or require clarification, please contact the Nuclear Materials Licensing Branch at (630) 829-9887.

Sincerely,

Original Signed By
Kevin G. Null
Nuclear Materials Licensing Branch

License No. 34-03643-01
Docket No. 030-05696

DOCUMENT NAME: M:\03005696.CL7

To receive a copy of this document, indicate in the box: "C" = Copy without attachment/enclosure "E" = Copy with attachment/enclosure "N" = No copy

OFFICE	DNMS/RIII								
NAME	KGNull:brt								
DATE	04/4/97								

OFFICIAL RECORD COPY

302456



UNITED STATES
NUCLEAR REGULATORY COMMISSION

REGION III
801 WARRENVILLE ROAD
LISLE, ILLINOIS 60532-4351

March 28, 1997

Cort N. Horton
Radiation Safety Officer
Merrill Pharmaceuticals, Inc.
2110 E. Galbraith Road
Cincinnati, OH 45215-6300

SUBJECT: ACKNOWLEDGEMENT OF CORRESPONDENCE
(Letter Dated 03/24/97)

Dear Licensee:

In response to your request, we have completed the initial processing, which is an administrative review of your application for a(n):

☐ New License ☒ Amendment ☐ Renewal
☐ Termination ☐ Auth User (Amendment not required)
☐ Other _____

No administrative deficiencies were identified during this initial review. However, it should be noted that a technical review may identify omissions in the submitted information.

It appears that your request is routine (see 1-3 below, as applicable).

1. New and amendment actions are normally processed within 90 days, unless we find major deficiencies, or policy issues requiring central program office assistance.
2. Renewal actions are normally processed within 180 days, however, under timely filing (before expiration), you may continue to operate under your existing license.
3. Termination actions are normally processed within 90 days, unless confirmatory surveys following decontamination/decommissioning activities are involved.

A copy of your correspondence has been forwarded to our Licensing Fee and Debt Collection Branch (301/415-6097) for approval of the fee category and amount, if required.

If you have a compelling safety or business-related reason for requesting expedited review, please contact the Materials Licensing Branch at (630) 829-9887. We will try to complete your request as soon as practicable. Any correspondence about this request should reference the control number.

Nuclear Materials Support Branch

Mail Control No. 302456
License No. 34-03643-01