

Enzon Pharmaceuticals, Inc.
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July 29, 2008

Licensing Assistance Team
Division of Nuclear Materials Safety
U.S. Nuclear Regulatory Commission Region I
475 Allendale Road
King of Prussia, PA 19406-1415

Dear sir or madam:

03033128
Enclosed is our completed Application for Materials License renewal of License Number 29-30031-01. A check for \$3,600 (check # 098037) has been sent separately to your office. Please acknowledge receipt of this application and contact me if there are any questions.

Sincerely,

A handwritten signature in black ink that reads "David Filpula".

David Filpula, Ph.D.
Radiation Safety Officer
Enzon Pharmaceuticals Inc.

Tel: 732-980-4941
Fax: 732-885-2950
E-mail: david.filpula@enzon.com

142645
NMSS/RGNI MATERIALS-002

NRC FORM 313
(4-2008)
10 CFR 30, 32, 33,
34, 35, 36, 39, and 40

U.S. NUCLEAR REGULATORY COMMISSION

APPROVED BY OMB: NO. 3150-0120

EXPIRES: 10/31/2008

Estimated burden per response to comply with this mandatory collection request: 4.4 hours. Submittal of the application is necessary to determine that the applicant is qualified and that adequate procedures exist to protect the public health and safety. Send comments regarding burden estimate to the Records and FOIA/Privacy Services Branch (T-5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by internet e-mail to infocollects@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0120), Office of Management and Budget, Washington, DC 20503. If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

APPLICATION FOR MATERIALS LICENSE

INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.

APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

DIVISION OF INDUSTRIAL AND MEDICAL NUCLEAR SAFETY
OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:

IF YOU ARE LOCATED IN:

ALABAMA, CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, FLORIDA, GEORGIA, KENTUCKY, MAINE, MARYLAND, MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, NORTH CAROLINA, PENNSYLVANIA, PUERTO RICO, RHODE ISLAND, SOUTH CAROLINA, TENNESSEE, VERMONT, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA, SEND APPLICATIONS TO:

LICENSING ASSISTANCE TEAM
DIVISION OF NUCLEAR MATERIALS SAFETY
U.S. NUCLEAR REGULATORY COMMISSION, REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PA 19406-1415

03033128
X

IF YOU ARE LOCATED IN:

ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND APPLICATIONS TO:

MATERIALS LICENSING BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, IL 60532-4352

ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, HAWAII, IDAHO, KANSAS, LOUISIANA, MISSISSIPPI, MONTANA, NEBRASKA, NEVADA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, OREGON, PACIFIC TRUST TERRITORIES, SOUTH DAKOTA, TEXAS, UTAH, WASHINGTON, OR WYOMING, SEND APPLICATIONS TO:

NUCLEAR MATERIALS LICENSING BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
612 E. LAMAR BOULEVARD, SUITE 400
ARLINGTON, TX 76011-4125

2008 AUG -1 PM 12: 22
RECEIVED
REGION I

PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S. NUCLEAR REGULATORY COMMISSION JURISDICTIONS.

1. THIS IS AN APPLICATION FOR (Check appropriate item)

- A. NEW LICENSE
- B. AMENDMENT TO LICENSE NUMBER
- C. RENEWAL OF LICENSE NUMBER 29-30031-01

2. NAME AND MAILING ADDRESS OF APPLICANT (Include ZIP code)

Enzon Pharmaceuticals, Inc.
20 Kingsbridge Road
Piscataway, NJ 08854

3. ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

Enzon Pharmaceuticals, Inc.
20 Kingsbridge Road
Piscataway, NJ 08854

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

David Filpula, Ph.D. (Radiation Safety Officer)

TELEPHONE NUMBER

(732) 980-4941

SUBMIT ITEMS 5 THROUGH 11 ON 8-1/2 X 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

5. RADIOACTIVE MATERIAL

a. Element and mass number; b. chemical and/or physical form; and c. maximum amount which will be possessed at any one time.

6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.

7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING EXPERIENCE.

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.

9. FACILITIES AND EQUIPMENT.

10. RADIATION SAFETY PROGRAM.

11. WASTE MANAGEMENT.

12. LICENSE FEES (See 10 CFR 170 and Section 170.31)

FEE CATEGORY **M** AMOUNT ENCLOSED \$ **3,600.00**

13. CERTIFICATION. (Must be completed by applicant) THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, 36, 39, AND 40, AND THAT ALL INFORMATION CONTAINED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.

WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.

CERTIFYING OFFICER -- TYPED/PRINTED NAME AND TITLE

Lee Greenberger, Ph.D. Vice President, Research

SIGNATURE

DATE

7/1/08

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED	CHECK NUMBER	COMMENTS
			\$		
APPROVED BY				DATE	

**Attachment to NRC FORM 313
Items 5 through 11**

License No. 29-30031-01 - RENEWAL

5. RADIOACTIVE MATERIALS

No changes to existing license.

Byproduct / Chemical Form / Maximum Amount

Hydrogen 3 / Any / 300 millicuries

Carbon 14 / Any / 70 millicuries

Phosphorus 32 / Any / 100 millicuries

Phosphorus 33 / Any / 100 millicuries

Sulfur 35 / Any / 100 millicuries

Chromium 51 / Any / 50 millicuries

Iodine 125 / Any / 50 millicuries

Iodine 131 / Any / 50 millicuries

6. PURPOSE FOR WHICH LICENSED MATERIAL WILL BE USED

No changes to existing license.

All materials listed in item 5: Research and development as defined in 10 CFR 30.4; *in vitro* lab studies and studies in small lab animals

7. INDIVIDUAL RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING EXPERIENCE

No changes to existing license.

David Filpula, Ph.D., is the Radiation Safety Officer of Enzon Pharmaceuticals Inc. He has over 10 years experience as a corporate RSO including experience in NRC interactions and inspections, personnel safety training, record maintenance, surveys, audits and investigations, materials control, and disposal control. The Authorized User will also be David Filpula (RSO and AU), who will directly use or supervise the use of the licensed material.

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS

No changes in existing license.

Radiation safety training will be provided by the RSO to all individuals, including Receiving, who work in a laboratory where radioisotopes are used prior to use of licensed materials. Training includes yearly refresher courses for workers directly using radioisotopes and will include videos, lectures, Q&A, feedback, and oral quizzes. Topics covered include the chemistry of radioisotopes, specific hazards for each licensed material, best practices in personal protective procedures for the licensed materials, decontamination and emergency procedures, ordering and routing of materials, NRC regulations, literature and contact information, monitoring of labs and dosimetry badges, and waste disposal.

9. FACILITIES AND EQUIPMENT

No changes to existing license.

The facility design and equipment are on record for License 29-30031-01 and we request no changes. Receipt of radioisotopes from a commercial shipper is checked into the log at a segregated area and monitored by the RSO (GM monitor and swipes) at the Receiving Department entrance. Radioisotopes are delivered to the designated laboratory and stored in a controlled access environment. The laboratories where radioisotopes may be used are restricted from access by other personnel and are not adjacent to unrestricted areas. Designated laboratories have all essential equipment such as proper material shielding (plastic, lead) and all employees wear personal protective garments and gloves. Dosimetry badges/rings are required. Fume hoods with dedicated air handling and filters are used for any potentially volatile materials. Dedicated and shielded radioactive waste disposal bags and containers with inventory logs will be present in the lab designated for radioisotope work and the RSO will monitor the contents and correct usage of disposal. A separate caged disposal area will be maintained for drums of radioactive waste prior to shipment by an authorized shipper or for storage and decay of short lived isotopes. GM monitors are on calibration schedules, and swipes for measurement of radioactivity are conducted by a commercial service provider. Live animals are not presently housed on-site at Enzon. If work is conducted with animals, the regulations of the external provider of animal facilities will be understood and followed. Enzon is a locked, secured, controlled facility and all visitors and employees are required to wear identification badges.

10. RADIATION SAFETY PROGRAM

No changes to existing program.

An audit program with periodic inspections will be implemented to monitor users of radioisotopes. Radiation monitoring instruments (GM monitors, swipes and dosimetry badges, LSC, Gamma Counters) are calibrated periodically. Procedures for the safe use and security of radioisotopes and emergency procedures have been developed. We have developed procedures for ensuring material accountability. Package and contamination surveys are conducted by the RSO. Waste disposal is controlled and monitored by the RSO. Bioassay, effluent release, and unrestricted area dose rate measurements are monitored by the RSO and by authorized commercial service providers. Physical

inventories will be conducted at intervals not to exceed 6 months, to account for all sealed sources and devices received and possessed under the license.

We will use instruments that meet the radiation monitoring instrument specifications published in Appendix M to NUREG – 1556, Vol. 7 ‘Program-Specific Guidance About Academic, Research and Development, and Other Laboratory Licenses of Limited Scope,’ dated December 1999. We reserve the right to upgrade our survey instruments as necessary.

We have done a prospective evaluation and determined that unmonitored individuals are not likely to receive, in one year, a radiation dose in excess of 10% of the allowable limits in 10 CFR Part 20.

We will survey our facility and maintain contamination levels in accordance with the survey frequencies and contamination levels published in Appendix Q to NUREG – 1556, Vol. 7, ‘Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope,’ dated December 1999. Leak tests will be performed at the intervals approved by NRC or an Agreement State and specified in the SSD Registration Certificate. Leak tests will be performed by an organization authorized by NRC or an Agreement State to provide leak testing services to other licensees or using a leak test kit supplied by an organization authorized by NRC or an Agreement State to provide leak test kits to other licensees and according to the sealed source or plated foil manufacturer’s (distributor’s) and kit supplier’s instructions.

11. WASTE MANAGEMENT

No changes to existing program.

We will use the model waste procedures published in Appendix T to NUREG – 1556, Vol. 7, ‘Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope,’ dated December 1999.